GE Healthcare

CardioSoft™ V7.0

Operator's Manual
Product Code SSG

Software Version 7.0

2096198-002 EN Revision G



NOTE: The information in this manual only applies to system software version 7.0. It does not apply to earlier software versions.

NOTE: CardioSoft V7.0 is referred as CardioSoft across the manual.

Due to continuing product innovation, specifications in this manual are subject to change without notice.



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CE Marking Information

Compliance

The product CardioSoft bears the CE marking CE 0459, notified body GMED, indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive. Date of the first CE mark - 1997.

The medical device has been assigned to class IIa as specified in Annex IX of the Directive 93/42/EEC.

The medical device has a lifetime of 5 years with respect to the Council Directive 93/42/EEC essential requirement #4.

The product complies with the electromagnetic immunity requirements of standard IEC 60601-1-2 “Electromagnetic Compatibility - Medical Electrical Equipment”.

The radio interference emitted by this device is within the limits specified in EN 55011 - class B.

MAGNETIC AND ELECTRICAL INTERFERENCE - Magnetic and electric fields can interfere with the system. Make sure that all peripheral components operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems (cellular phones) and so forth, are possible sources of interference because they may emit higher levels of electromagnetic radiation. Verify the performance of the system before use.

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the system cart comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems, cellular telephones, etc. are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the system cart away from these devices and verify the performance of CardioSoft before use.

The safety and effectiveness of this device has been verified against previously distributed devices. Although all standards applicable to presently marketed devices may not be appropriate for prior devices (i.e., electromagnetic compatibility standards), this device will not impair the safe and effective use of those previously distributed devices (see Operator’s Manual).

The country of manufacture appears on the device label.

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1 Introduction

For your notes

License Agreement

Opening the envelope indicates acceptance of the license agreement. If you do not accept the terms of this agreement, return the closed envelope including the documentation and supplied hardware to your vendor for a full refund.

The object of the agreement is to grant a license for the use of the software program and product documentation. GE Healthcare grants you the personal, non-exclusive and non-transferable right to use the software. The software and documentation are protected by copyright laws. The licensee agrees to observe the regulations stipulated by the copyright. The software and all rights to it remain the property of GE Healthcare. The enclosed copy of the program may be installed only one computer. You may not transfer the software via network or other communication channels to any other computer. The program and the accompanying documentation may not be modified, copied, merged with other programs, or made available to third-parties. The licensee is liable for any damage to the licenser resulting from infringement of the copyright as per this license agreement. The licenser notifies all users that the present state of the art does not allow for the creation of computer programs which run trouble-free in all applications and combinations. The licenser is not liable for product malfunctions. The licenser is not obliged to make program updates available to licensees who have not signed and returned the registration card.

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About This Manual

Revision History

This manual is subject to the GE Healthcare change order service. The revision code, a letter that follows the document part number, changes with every update of the manual.

Table 1: Revision History

Part No./ Revision	Date	Comment
A	2018-03-12	Initial release.
B	2018-03-12	Initial release.
C	2018-12-18	Initial release.
D	2018-12-18	Customer release.
E	2020-04-07	Updated Initial Screen image. Added treadmill speed compatibility.
F	2020-07-28	Updated InSite Information
G	2021-02-04	Added CardioSoft Console references

Manual Purpose

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

Where necessary the manual identifies additional sources of relevant information and/or technical assistance.

Intended Audience

This manual is geared for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for completing these examinations.

Illustrations

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

All names appearing in examples and illustrations are fictitious. The use of any real person's name is purely coincidental.

Safety Information

Intended Use

- CardioSoft is intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients.
- CardioSoft is designed to acquire, process, record, archive, analyze and output ECG data (12 and 15 leads) during a period of physiologic stress or during a resting ECG test and acquire data from ancillary devices, such as spirometry and ambulatory blood pressure devices. Furthermore, it provides median morphology recordings and records ECG in real-time with and without arrhythmia detection.
- The arrhythmia detection algorithm of CardioSoft is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.
- CardioSoft provides the control of external devices. These are typically treadmills and bicycle ergometers. Additionally, CardioSoft communicates with centralized electronic/digital storage systems via data networks.

WARNING
Patient Hazard—Do not use the digital or analog outputs to control therapeutic devices such as defibrillators.

- CardioSoft provides a user-selectable option for printouts of prognostic scores on selected reports. Vector loops are also available.
- CardioSoft can be configured in a network environment for multiple CASE and CardioSoft stations allowing the user to create a central database of patient demographics and collected patient physiological data.
- CardioSoft is intended to be used primarily in the hospital. However, it can also be used in clinics, physician offices, outreach centers or wherever exercise stress testing, ECG, spirometry or ambulatory blood pressure testing is performed.
- CardioSoft offers no diagnostic opinion to the user. Instead it provides interpretive statements of morphology, rhythm, and conduction for which the physician renders his/her own medical opinion.
- CardioSoft is not intended to be used as a transport device or for home use.
- CardioSoft is not intended for use as a vital signs physiological monitor.
- CardioSoft is not intended for intracardiac use.
- CardioSoft is not intended for use as an emergency device.
- CardioSoft will not cause abnormal operation of a patient's cardiac pacemaker or other electronic stimulators.

- CardioSoft is not intended for use with high frequency surgical units. Disconnect the patient from CardioSoft before using the high frequency surgical unit.

General Information

- This manual is an integral part of the product. It should always be kept near the product. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. Read the manual once in its entirety, because information pertinent to several chapters is given only once.
- To ensure maximum patient safety, interference-free operation and the specified measuring accuracy, we recommend using only original GE Healthcare accessories. The user is responsible for application of accessories from other manufacturers.
- The warranty does not cover damage resulting from the use of unsuitable accessories and consumables from other manufacturers.
- GE Healthcare is responsible for the effects on safety, reliability, and performance of the product, only if:
  - Assembly operations, extensions, readjustments, modifications, or repairs are carried out by GE Healthcare or by persons authorized by GE Healthcare.
  - The electrical installation of the relevant room complies with the requirements of the appropriate regulations, and
  - The product is used in accordance with the instructions given in this manual.
- This equipment is protected against the effects of cardiac defibrillator discharge to ensure recovery as required by test standards.
- Accuracy of the Input Signal Reproduction:
  - Recording speed accuracy is tested using the method described in IEC 60601-2-25 and the maximum error is ± 5 %.
  - Frequency Response is tested according to IEC 60601-2-25 and methods A and D.
- Modulating Effects in the Digital System.

  This device uses digital sampling techniques that may produce some variation in amplitude of Q, R, and/or S waves. This effect may be particularly noticeable in pediatric recordings. If this phenomenon is observed, the clinician should be aware that the origin of amplitude variations is not entirely physiologic. For measuring voltages of Q, R, and S waves, it is advisable to use the QRS complexes with the largest deflection of the particular waves.

- Contact GE Healthcare for information before connecting any devices to this system that are not recommended in this manual.
- Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.The use of accessories not

complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Considerations relating to the choice shall include:

- Use of the accessory in the patient vicinity.
- 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.

- Throughout the document, GEH-ECG 1200 refers to the Wireless GEH-ECG 1200 acquisition module, GEH-ECG 1200W refers to the transmitter unit, and GEH-ECG 1200WR refers to the receiver unit of the acquisition module.

Definition

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.

The safety statements presented in this chapter refer to the equipment in general.

The order in which safety statements are presented in no way implies order of importance.

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, may result in minor personal injury or product/property damage.

Danger
EXPLOSION HAZARD — The acquisition moduleis not designed for use in areas of medical locations where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants. The acquisition moduleis suitable for application in an oxygen-enriched atmosphere only with certain restrictions. The atmosphere is considered to be oxygen-enriched when the room air contains more than 25 % of oxygen or nitrous oxide.

Warning
SHOCK HAZARD — Observe the following warnings. Failure to do so endangers the lives of the patient, the user, and other persons present.

- Only specially trained technical staff is authorized to open the connector access panel.
- Before putting the device into operation, the operator is required to ascertain that it is in correct working order and operating condition. The cables in particular, must be checked for damage. Damaged cables and connectors must be replaced immediately.
- ISOLATION FROM SUPPLY MAINS - Do not position the system so that it is difficult to disconnect the AC power supply. Choose a location where the power connector is readily accessible at all times, if problems occur. To disconnect the system from the power line, remove the plug from the wall outlet first. Otherwise, there is a risk of coming in contact with line voltage by inadvertently introducing metal parts in the sockets of the power cord.
- Do not use extension cables with multiple portable socket outlet (MPSO).
- All devices of a system must be connected to the same power supply circuit. Devices that are not connected to the same circuit must be electrically isolated for operation (electrically isolated RS232 interface); this requirement does not apply in the USA.
- The acquisition module is not intended for intracardiac use.
- The computer must be installed outside the patient vicinity if it does not meet the requirements of IEC 60601-1.
- All bicycle ergometers and treadmills connected to the system must meet the requirements of IEC 60601-1. CardioSoft and the connected bicycle ergometer or treadmill must be connected to the same electric circuit through separate wall outlets; this requirement does not apply in the USA.

Warning
SHOCK HAZARD — Observe the following warnings. Failure to do so endangers the lives of the patient, the user, and other persons present.

- All modems connected to the system must meet the requirements of IEC 60950. The specific regulations valid in your country must also be observed.
- The modem must be installed within the medical location, but not in the patient vicinity.
- Disconnect the patient from the computer while sending data via the modem.
- Devices may only be connected to each other or to parts of systems when it has been made certain that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of devices. Standards IEC 60601-1-1/EN 60601-1-1 must be complied with in all cases.
- Liquids must not be allowed to enter the device. If liquids have entered the devices, take it out of service and have it checked by a service technician before using it again.
- EQUIPMENT MALFUNCTION — Any attempt by unauthorized personnel to service, the device could result in equipment malfunction, and void the warranty. This equipment contains no user-serviceable parts. Refer servicing to authorized service personnel.
- ELECTRIC SHOCK — Improper connection of this equipment may cause electric shock. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Warning
SHOCK HAZARD — Observe the following warning. Failure to do so endangers the lives of the patient, the user, and other persons present.

- Use only the original GE Healthcare patient cable. Do not connect other signal sources to the cable.

Warning
PATIENT HAZARD — During exercise tests, a defibrillator and a pacemaker, both checked for proper functioning, should be kept at hand.

PATIENT HAZARD — The operator must be capable of using the equipment properly.

INTERPRETATION HAZARD — A qualified physician must over read computer-generated tracings. Computerized interpretation is only significant when used in conjunction with clinical findings.

RISK OF SUFFOCATION — Dispose of the packaging material, observing the applicable waste-control regulations and keeping it out of children's reach.

RISK OF POISONING — Follow all manufacturer instructions for preparing and storing chemicals required for the application or maintenance of the device, and store all chemicals in their original containers to prevent poisoning risk.

EQUIPMENT MALFUNCTION/INTERFERENCE - Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Do not use portable phones or other electronic equipment that may emit radio frequency (RF) near this system.

Caution

LOSS OF DATA — Improper shutdown of the CardioSoft system might damage the database. For example, turning the system off with the mains power switch before all programs are closed.

Warning

Risk of Injury-Crush Hazard — Avoid placing your feet under the cart during transport. Your feet may be crushed.

PERSONAL INJURY - Contact with patients during defibrillation can cause serious injury or death.
Do not contact patients during defibrillation. Patient signal inputs labeled with the CF symbols with paddles are protected against damage resulting from defibrillation voltages.
To ensure proper defibrillator protection, use only GE Healthcare recommended cables and leadwires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

Caution

EQUIPMENT DAMAGE — Before connecting the device to the power line, check that the voltage and frequency ratings of your power line match those indicated on the device label.

LOSS OF DATA — To avoid loss of data, make a daily backup of the program and database folders (as determined during installation).

RESTRICTED SALE — Federal Law restricts this device to sale by or on the order of a physician.

PASSWORD PROTECTION — If access to the system is protected with a password, the password must be stored in a secure place and made available to registered system users. You must change your password, when prompted.

ACQUISITION MODULE — Connect the system only with the CAM CONNECT 14 (CC14) or the Wireless GEH-ECG 1200 acquisition module.

EQUIPMENT CONFIGURATION — The equipment or system should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, test the equipment or system to verify normal operation.

INTERCONNECTED DEVICES - When several items of medical equipment are interconnected, summation of leakage current must meet the leakage current as per IEC 60601-1.
Connect the device only to the GE approved supplies and accessories.

Classification

Type of protection against electrical shock	**Class II**
Degree of protection against electrical shock	**Type CF, defibrillation-proof applied parts - ECG leads**
Degree of protection against harmful ingress of water	**Enclosed equipment without protection against ingress of water**
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	**Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.**

Method(s) of sterilization or disinfection recommended by the manufacturer	**Sterilization: not applicable disinfection: see Appendix A**
Mode of operation	**Continuous operation**

Equipment Symbols

Note

Some of the symbols may not appear on all equipment.


Caution, consult accompanying documents.


Consult instructions for use.


Type CF signal input, defibrillation-proof.


Mains power switch (ON - OFF)


Follow Instructions for Use. Read and understand the operator's manual before using the product.
As a mandatory action sign, this symbol is identified by a blue background and white symbol.

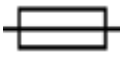

Potential equalization pin

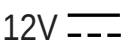

Protective earth terminal


Caution! High Voltage!


Signal input


Signal output


Fuse



12 V DC


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



Authorized representative in the European Community.

CE 0459 — CE marked per the Medical Device Directive 93/42/EEC of the European Union.

Manufacturer's identification

REF — Order number

REV — Revision letter

SN — Serial number

ID — Ident number

LOT — Lot number

Mass

PID — Product ID (3 digits)

EAC — Eurasian Conformity mark.
Conformity to applicable technical regulations of Customs Union.

IPxx — **IP Code (Ingress Protection Rating)**
Classifies and rates the degree of protection provided against the intrusion of solid objects (such as body parts like hands and fingers, dust, accidental contact), and liquids.
The first numeral (x) represents the degree of protection against the ingress of solid objects.
The second numeral (x) represents the degree of protection against the ingress of liquids.
For products with an IPxx rating, see the Classification of Medical Device in this chapter for a description of that rating. Not all products have an IPxx rating.

Medical Equipment
With respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1, and CAN/CSA C22.2 NO. 601.1.

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

China RoHS pollution control label

China RoHS Mobius loop symbol

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

Rx Only Caution: Federal law restricts this device to sale by or on the order of a physician.



Unique Device Identification is a unique marking for identification of the medical device.



Class II equipment.

Unique Device Identifier (UDI)

Medical devices require a unique marking for identification—the Unique Device Identifier (UDI). In the event that you need to access the UDI for this software product, on the menu bar select System Info.

If the UDI does not display, contact your GE Healthcare service representative.

Supplies and Accessories

Refer to the Supplies and Accessories Guide (2102946-001), Diagnostic Cardiology, for supplies and accessories, ordering, safety, and cleaning information for your device.

Biocompatibility

All parts of the product and all accessories described in this manual that come in contact with the patient during the intended use of the product, fulfill the biocompatibility requirements of the applicable standards. If you have questions in this matter, contact GE Healthcare or its representatives.

Technical Maintenance

For technical data and other detailed technical information, see Service Manual. The product is compliant with EN/IEC 60601-1-2 and applicable amendments. Refer to the Electromagnetic Immunity information in the product's service manual.

Legal Notice

Our equipment contains several fields which can be filled in before performing an ECG. Some of these fields must be filled in before performing an exam, some are optional and therefore left to the user to assess whether they are needed to perform the exam. A field RACE is one of these optional fields. It has been acknowledged by the medical profession as useful to analyze some pathologies. You should be aware that, in some jurisdictions, the processing of data revealing an individual's racial origin is subject to legal requirements, such as

obtaining the patient's prior consent. If you elect to collect this type of data, it is your responsibility to ensure that you comply with all applicable legal requirements.

Security Patches

Visit the GE Healthcare Product Security Database regularly and search for security patches for your product in order to keep the operating system up to date and ensure its integrity. Download the security patch compatible with your operating system and install it on your system.

Registration and download: http://prodsecdb.gehealthcare.com

Service Information

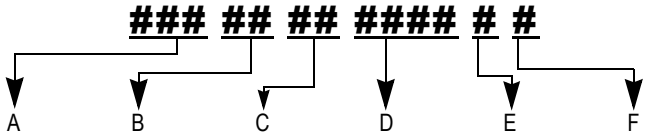
Service Requirements

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

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

Equipment Identification

Every GE Healthcare device has a unique serial number for identification. The serial number appears on the device label.



A Product Code
B Year Manufactured (00-99)
00 = 2000, 01 = 2001, 02 = 2002 (and so on)
C Fiscal Week Manufactured
D Production Sequence Number
E Manufacturing Site
F Miscellaneous Characteristics

2 Product Overview

For your notes

PC / Server Setup

Minimum PC / Server Requirements

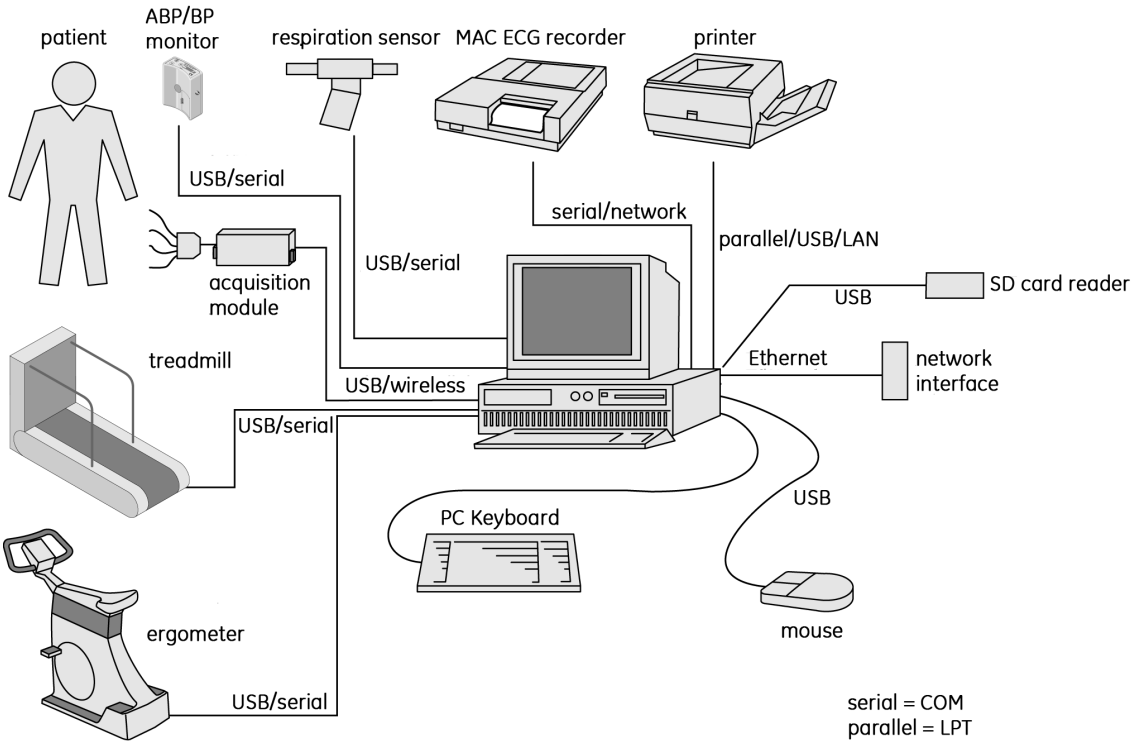
For the minimum PC and server requirements, refer to the Cardiosoft Software Installation and Upgrade Guide.

Peripheral Devices Connecting to the PC

The illustration below shows the PC interfaces where peripheral devices can be connected.

WARNING
RADIO INTERFERENCE — In residential areas, devices and installations with radio-interference protection according to EN 55011, Class A, may be disturbed by radiation emitted by the PC system. In this case, the user is required to take appropriate measures.

Refer to the Electromagnetic Immunity information in this product's service manual for EN 60601-1-2 compliance information and safety information for this product.



Note

If the acquisition module is CC14, it is recommended to be used on USB 3.0 ports. Ensure that you have updated BIOS in system.

MAC 600, MAC 800, MAC 1600, MAC 2000, MAC 3500, MAC 5000, MAC 5500

The ECG systems can be connected to a PC through the serial interace meeting the minimum GE Healthcare requirements. For more information, contact the GE Healthcare Customer Service. This combination of devices allows you to transfer resting ECGs acquired in the automatic mode to the PC, including the pertinent data.

Make sure to read the safety information in section "Safety Information" on page 1-5. IEC standard 60601-1-1 must be complied with in any case.

For installation instructions, refer to the Cardiosoft Software Installation and Upgrade Guide.

Caution

PATIENT HAZARD — Always connect the CAM-14 acquisition module to the CAM-USB/CAM-USB A/T interface box, do not connect directly to the PC.

DISCONNECTING LEADWIRES — Always attach the CAM-USB/CAM-USB A/T interface box to a suitable place (for example, on the PC)

SHOCK HAZARDS/EQUIPMENT DAMAGE — The patient signal input is a high-insulation port and it is defibrillation-proof (type CF). This type of input guarantees patient safety and protects the equipment during defibrillation and HF surgery. Nevertheless, extreme care should be exercised when a defibrillator or HF surgery equipment is used on a patient connected to other devices. As a general rule, the distance between the ECG electrodes and the defibrillation or HF surgery electrodes should not be less than 15 cm. If this is not ensured, temporarily disconnect the patient cables while using the defibrillator or the HF surgery equipment. It is very important that conductive parts, such as connectors, electrodes, or transducers, do not come into contact with other grounded, conductive parts when connected to the isolated patient input. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

Note

Before starting the CardioSoft program, verify that the acquisition module is connected to the PC and that the AC power adapter is connected, if required. If the acquisition module is not connected, the system cannot read the internal serial number and all option codes will become invalid.

Note

Set up the device so that the operator has a clear, unobstructed view of the control panel.

Only persons with the required training and expertise are authorized to use medical electrical equipment such as a PC with CardioSoft.

CardioSoft Client/CardioSoft Web Hardware Key

For use of the optional software packages

- CardioSoft Client
- CardioSoft Web

A hardware key is required for workstations that are integrated in the network and have no acquisition module. Depending on the hardware key used, it is connected either to the printer port or to a USB port.

Note

It is not possible to operate both the acquisition module and the hardware key at the same workstation.

When using the *Floating License*/*CardioSoft Web* software option, the hardware key must be installed at the server (in conjunction with Windows Server 2008 R2, Windows Server 2012, Windows Server 2012 R2, and Windows Server 2016).

Installing CardioSoft

For CardioSoft installation instructions, refer to the Cardiosoft Software Installation and Upgrade Guide.

Note

To ensure GEMS-IT Acquisition Diagnostics properly opens, do not run the anti-virus scan during CardioSoft installation.

Putting the System Into Service

The software is a Windows-based program. Its scope can be expanded by activation of individual optional programs. This manual describes the program with all options included. If you have not purchased one or the other option, simply skip the corresponding sections.

Access to the program is restricted to registered users. At the time a user is registered, the password and privileges are assigned (technician, physician, with or without the right to edit data, etc.).

Mains Connection, Power Up, Functional Test

1. Before powering the system up for the first time, read the safety information in section "Safety Information" on page 1-5.
2. Turn on the PC, the monitor and, if used, the bicycle ergometer or treadmill, electrocardiograph and printer.
3. Double-click the CardioSoft icon to start the program.

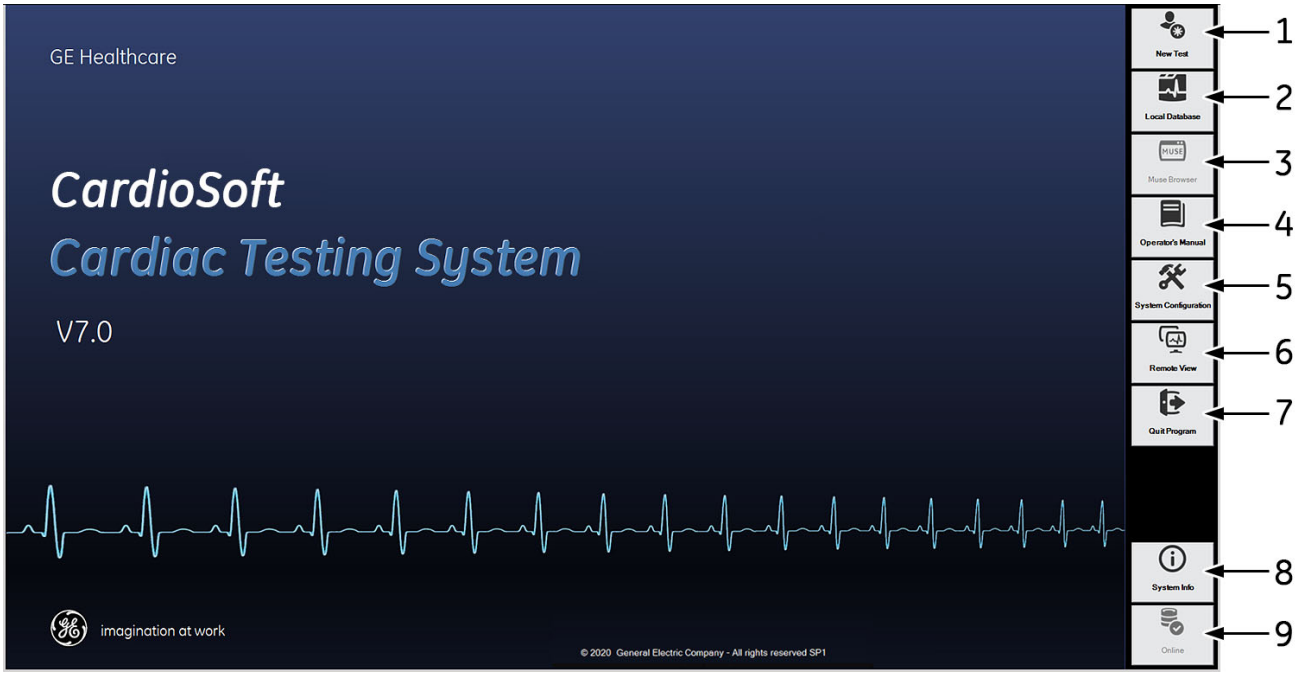
When you see the initial screen (see "Initial Screen" on page 2-7) and no error message appears, the program is operational.

Note

- Do not run more than one additional Windows-based program at the same time as CardioSoft.
- The screen saver is automatically disabled during ECG acquisition.
- When using the program for the first time, select the size of your monitor screen ("General Tab" on page 12-35).
- Disable all energy save modes (BIOS, Windows).
- Unlock the purchased optional software programs as described in section "Option Code Tab" on page 12-45.
- Scan the hard drive for viruses once a week.
- Do not turn off the PC until you have properly exited from the program and shut down Windows.
- Run a functional test on a regular basis (about once a month); this includes an inspection of the cables and other accessories for signs of damage.

Caution
SIMULATED PATIENT DATA — To avoid the possibility of misinterpreting patient information, enable the simulated Test Patient data for demonstration purposes only.

Initial Screen



1 *New Test.*

2 *Local Database* displays the contents of the local database for selection of a patient and test.

3 *MUSE Browser* opens the MUSE system database.

4 *Operator's Manual.*

5 *System Configuration.*

6 *Remote View* to view exercise tests performed at remote stations.

7 *Quit Program.*

8 System Information

9 Online to view online databases.

Note

Refer to section "Country Settings Tab" on page 12-46 for information on selecting the language and on toggling between text labels and icons, or right-click any button to toggle between text labels and icons.

Softkeys Controlling Exercise Tests

Softkeys for control of the exercise test are displayed at the bottom of the screen; you activate these keys by clicking them with the mouse. Some of the softkeys can also be activated with the function keys **F1** through **F12** on the keyboard.

Note

start tmill, speed+, and exercise (next stage) will be blocked while treadmill is in emergency stop mode.

Following is a brief explanation of the key functions. For detailed information on running the exercise test, refer to section "Before the Test" on page 6-6.



F1: pretest	initiates the pretest phase and advances through the pretest stages (to return to the preceding stage, press Shift + F1 or Shift + *F1:pretest*).
F2: exercise	initiates the exercise phase and advances through the individual stages of the exercise phase.
F3: recovery	initiates the recovery phase and advances through the individual stages of the recovery phase.
F4: test end	terminates the test and initiates the printout of the final reports.
arrhy doc	enables and disables automatic arrhythmia reporting.
hold stage	maintains the current stage (automatic stage sequencing is stopped). Press again to turn off stage hold.
F5: speed + **or** *load* +	increases the treadmill speed or ergometer workload.
F6: speed - **or** *load* -	decreases the treadmill speed or ergometer workload.
F7: grade up	increases the treadmill grade.
F8: grade down	decreases the treadmill grade.
F9: start tmill	starts the belt. When restarted after FAST stop, the treadmill returns to the previous speed and grade.
F10: stop tmill	stops the belt.
F11: comment	enables entry of additional information and of values for the user-defined columns of the tabular summary (see "Configuring the Tabular Summary" on page 12-9).
F12: enter BP	enables entry of the patient's blood pressure readings.
12 lead	initiates recording of a 10-second ECG (5 seconds from memory, 5 seconds from when key was pressed).
medians	initiates printout of a medians report.
rhythm	initiates recording of a continuous, real-time ECG rhythm strip (terminate recording with *stop writer*).
recall	records a one-page rhythm strip of the previous 10 seconds.
12SL analysis	initiates a 12SL report (includes measurement report and interpretation - only available during pretest and recovery phases).

Viewing and Printing the Operator's Manual

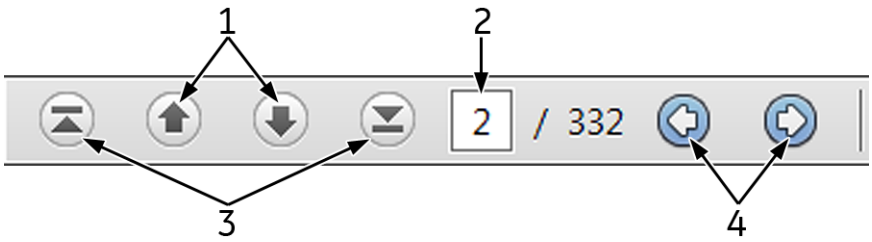
The CardioSoft operator's manual is available on the program CD-ROM.

Click *Operator's Manual* on the initial screen to display the document.

The system will load the *Acrobat Reader* program and display the title page of the operator's manual. Use the controls explained below to navigate through the document.

Note

Clicking a chapter headline in the operator manual's table of contents takes you directly to the corresponding chapter. Clicking an index entry will also display the corresponding page of the manual.



1 Move page back or forward through the document.

2 Displays the page number. Enter the page number you want to view and press Enter on the keyboard.

3 Takes you directly to the first or last page of the document.

4 Undoes a change of page or view.

To print the document:

1. Select *File* in the menu bar, then *Print*.
2. In the print dialog, choose the print options:
   - the *Print Range* (all pages, the current page, or a section of the document)
   - the print quality
   - the number of copies.
3. Click *OK* to initiate the printout.

Online Help

On many screens you will find a *Help* button. Click the button to display a context-sensitive Help window.

Note

The online help implemented in the software provides information about using the program. For safety information, refer to the Operator Manual and all other documents supplied with the product.

Software Options

Many features are available as options which can be unlocked to enhance the CardioSoft functionality. Following is a list of these optional features. For details, contact your Sales Representative.

RESB (Basic Software Package)

- 12-lead/15-lead ECG acquisition (resting ECG)
- downloading of data from MAC electrocardiographs
- data management for all modalities

RESM (Resting ECG Measurement)

- measurement of 12/15 simultaneously acquired leads
- tabular presentation of measured values
- manual editing of measuring marks
- direct comparison of 2 resting ECGs

RESI (Resting ECG Interpretation)

- interpretation of the measured resting ECG with detailed explanations
- medication and patient's age are taken into account
- reanalysis after manual modification of the measuring marks (not with 12SL)

ERGM (Remote View)

- during an exercise test, data is continuously sent via the network
- the following information is available at any of the workstations in the network:
  - station name
  - 12-lead ECG, leads selectable
  - information on the exercise test and ergometer
  - HR and blood pressure

EGMO (Storage of the Full-Disclosure ECG)

- continuous storage of a maximum of 15 leads
- color-coded arrhythmias
- any segment of the full-disclosure ECG can be zoomed and stored

NETS (Data Storage on Network Server)

- storage of examination data on low-volume server (< 3000 examinations)
- storage of examination data in the MUSE database
- use of the MUSE patient list to retrieve data

NET2 (Data Storage on Network Server)

- storage of examination data on medium-volume server (< 15,000 examinations)
- pre-condition: NETS required

NET3 (Data Storage on Network Server)

- storage of examination data on high-volume server (unlimited number of examinations)
- pre-condition: NET2 required

ARRY (Arrhythmia Documentation)

- arrhythmia documentation during exercise tests

2DWF (2D Waterfall Display)

- waterfall display during exercise tests and in exercise test report

BRWS (MUSE Browser)

- Internet browser for access to the MUSE system

RISK (Risk Factors)

- calculation of coronary heart disease and stroke risk factors
- Duke Treadmill Score

EXPD (Data Export)

- export of examinations in XML or Excel file format

EPDF (Report Export as PDF File)

- export of report as a PDF formatted file (we recommend Acrobat V5.0 at minimum)

EWRD (Report Export as Word File)

- export of the configured report as a Word formatted file (we recommend MS Word 2000 at minimum)

DSPC (Display Configuration)

- configuration of the vital-signs window

ITBL (In-Test Tabular Summary)

- display of the tabular summary during exercise tests

ITRD (In-Test Trend)

- display of trends during exercise tests

PRVT (Previous Test Retrieval)

- display of the previous exercise test during an exercise test

TWAA (T-Wave Alternans)

- T-wave alternans analysis of an exercise test

- required option code: EGMO

ERG2 (Exercise Test AT)

- ST measurement, arrhythmia (6/12 leads)

ERG3 (Exercise Test Expert Mode)

- manual editing of the E, J, and post-J point
- direct cross-referencing from the trends to the full-disclosure ECG (final report)
- 15-lead exercise test

ECGH (ECG History - requires hardware key)

- display of the median beats from up to 5 selected resting ECGs for comparison or printout
- 3D presentation of the median beat for serial comparison

DICM (DICOM Interface)

- software package for communication with the DICOM interface

STHY (ST/HT Hysteresis)

- 4 more exercise stress test values (ST/HR hysteresis, HR recovery, HR reserve used, FVE recovery)

EXTI (Exercise Test Interpretation XTI)

- evaluation of the exercise stress test with respect to:
  - risk of mortality
  - functional capacity
  - coronary heart disease
- required option codes: ERG2, STHY
- recommended option codes: TWAA, RISK

CWEB (Web Interface)

- display of patient records via the internet (section "CardioSoft Web" on page B-19)

XEMR (EMR Interface)

- software package for communication with the EMR interface

FLLX (Floating License)

- software package required if more than one person will use the program at the same time; the number of licenses varies with the purchased option code; requires hardware key to be connected to the server

CardioSoft Client

- software version for editing of patient records at workstations without acquisition module

Demo Version of CardioSoft

When working with the demo version of CardioSoft, the following points should be noted:

- The Test Patient is always selected (artificial patient signals). The demo version is not intended for use on patients.
- The acquisition module, the respiration sensor and TONOPORT cannot be connected.
- All available software options are active.
- The functions *Copy Patient Records*, *Receive Data from ECG Device*, *Archive Patient Records* are not available

3 Preparing the Patient

For your notes

Applying Electrodes - The Basics

Carefully apply the electrodes to obtain a noise-free ECG. In exercise testing, careful preparation of the patient's skin is a must (see section "Preparing the Patient" on page 3-4).

For resting ECGs, use GE Healthcare's electrode application system. Use only the GE Healthcare-recommended electrodes and contact agents.

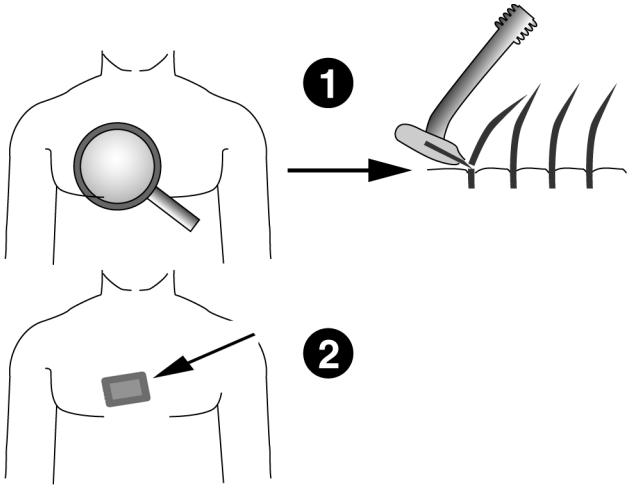
The signal acquisition screen will show the applied electrodes and the signal quality after the right-arm electrode has been applied. When the right-arm electrode becomes detached, the system behaves as if all electrodes were disconnected.

Observe the information given in sections "Recording ECGs of Pacemaker Patients" on page B-6 and "Recording ECGs During Defibrillation" on page B-6.

Warning
STRANGULATION HAZARD — Route cables and tubes away from patient's throat to avoid possible strangulation.

Caution
ELECTRIC SHOCK - Touching the conductive elements cancels the protection provided by the isolated signal input.Ensure that conductive parts of the electrodes or leadwires, including the neutral electrode, do not come in contact with other conductive parts, including earth.

Preparing the Patient



1. Shave hair from each electrode site and swab with alcohol.
2. Remove the epidermal skin layer with an abrasive pad or skin prep cream.

Caution
SKIN LESIONS — Do not rub the skin vigorously to avoid inflammation or bleeding.

Applying Electrodes

Lead Labels on the Acquisition Module

Warning
STRANGULATION HAZARD — Route cables and tubes away from patient's throat to avoid possible strangulation.

CAM CONNECT 14/Wireless GEH-ECG 1200

AHA Label	IEC Label
RL	N
RA	R
LA	L
LL	F
V1	C1
V2	C2
V3	C3
V4	C4
V5	C5
V6	C6
A1	A1
A2	A2
A3	A3
A4	A4

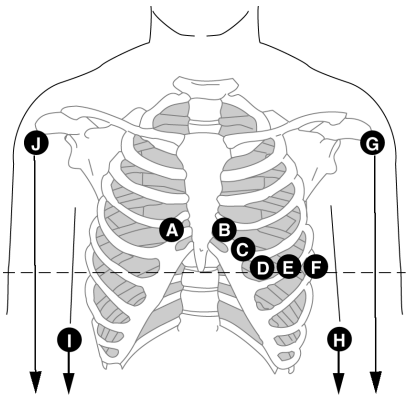
Warning
PATIENT HAZARD—The acquisition modules and interface boxes cannot identify pulses from artificial cardiac pacemaker; therefore, using them to control therapeutic devices, such as defibrillators, could lead to ventricular fibrillation or death due to incorrect or inaccurate QRS detection.

Do not use the output to trigger therapeutic devices.

Caution
PROPER LEADWIRE CONNECTION — Improper connection will cause inaccuracies in the ECG.

Trace each individual leadwire from its acquisition module label to the colored connector and then to the proper electrode to ensure that it is matched to the correct label location.

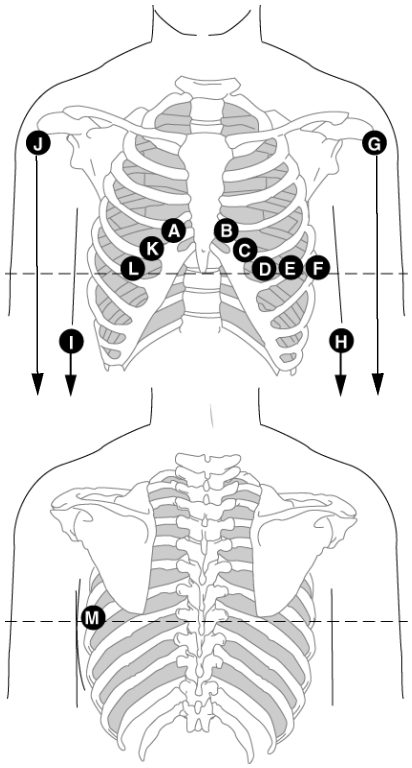
Standard 12 Lead Electrode Placement



	AHA Label	IEC Label	Electrode Placement
A	V1 red	C1 red	Fourth intercostal space at the right sternal border.
B	V2 yellow	C2 yellow	Fourth intercostal space at the left sternal border.
C	V3 green	C3 green	Midway between sites B and D.
D	V4 blue	C4 brown	Mid-clavicular line in the fifth intercostal space.
E	V5 orange	C5 black	Anterior axillary line on the same horizontal level as D.
F	V6 purple	C6 purple	Mid-axillary line on the same horizontal level as D.
G	LA black	L yellow	Left arm (resting ECG).
J	RA white	R red	Right arm (resting ECG).
H	LL red	F green	Left foot (resting ECG).
I	RL green	N black	Right foot (resting ECG).

Standard 15 Lead Electrode Placement

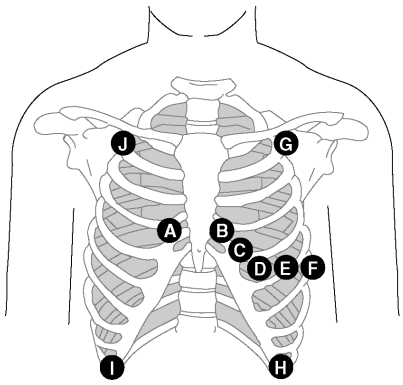
Standard leads + right, recommended for pediatric ECGs.



	AHA Label	IEC Label	Electrode Placement
A	V1 red	C1 red	Fourth intercostal space at the right sternal border.
B	V2 yellow	C2 yellow	Fourth intercostal space at the left sternal border.
C	V3 green	C3 green	Midway between sites B and D.
D	V4 blue	C4 brown	Mid-clavicular line in the fifth intercostal space.
E	V5 orange	C5 black	Anterior axillary line on the same horizontal level as D.
F	V6 purple	C6 purple	Mid-axillary line on the same horizontal level as D.
G	LA black	L yellow	Left arm (resting ECG).
J	RA white	R red	Right arm (resting ECG).
H	LL red	F green	Left foot (resting ECG).
I	RL green	N black	Right foot (resting ECG).
K/A3	V3R gray	C3R gray	Opposite of C.
L/A2	V4R gray	C4R gray	Opposite of D.
M/A1	V7 gray	C7 gray	Left posterior axillary line at the level of D.

MASON-LIKAR Lead Electrode Placement

(Modified Standard Leads for Exercise Tests)



	AHA Label	IEC Label	Electrode Placement
A	V1 red	C1 red	Fourth intercostal space at the right sternal border.
B	V2 yellow	C2 yellow	Fourth intercostal space at the left sternal border.
C	V3 green	C3 green	Midway between sites B and D.
D	V4 blue	C4 brown	Mid-clavicular line in the fifth intercostal space.
E	V5 orange	C5 black	Anterior axillary line on the same horizontal level as D.
F	V6 purple	C6 purple	Mid-axillary line on the same horizontal level as D and E.
G	LA black	L yellow	Slightly below the right and left clavicle.
J	RA white	R red	
H	LL red	F green	Lower edge of the rib cage, or at the level of the umbilicus at the left and right mid-clavicular lines.
I	RL green	N black	

Note

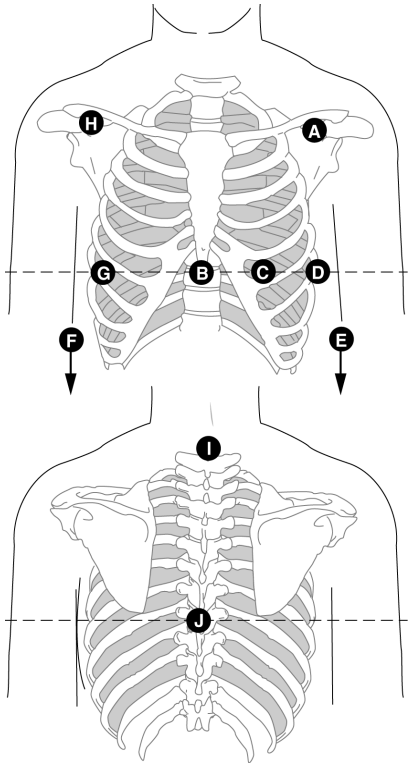
The ECG recorded with the torso placement of the limb lead electrodes may differ from that recorded with the electrodes on the limbs. Affected characteristics are the Q-waves and the frontal axes, whereas ST levels are unlikely to change.

This lead placement is the preferred placement for exercise stress tests on treadmills or bicycles with patients in the supine or half-supine position.

For upright bicycle exercise stress tests, it is recommended to apply the limb leads on the back opposite to the limb electrode positions shown above.

FRANK X, Y, Z Lead Electrode Placement

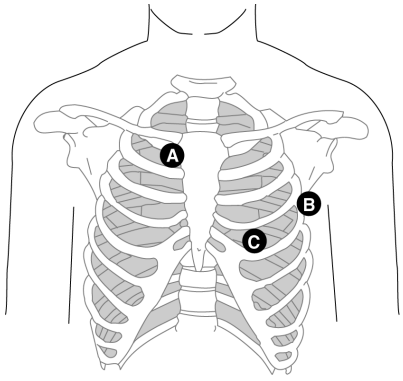
To record the orthogonal FRANK leads X, Y, and Z, apply electrodes G (A3), B (A2), J (A4) and I (A1) in addition to the standard lead electrodes.



	AHA Label	IEC Label	Electrode Placement
A H	LA black RA white	L yellow R red	Below the clavicle.
B/A2	E orange	E light blue	Sternum at the level of C and D.
C	V4 blue	C4 brown	Mid-clavicular line in the fifth intercostal space.
D	V6 purple	C6 purple	Left mid-axillary line on the same horizontal level as C.
E F	LL red RL green	F green N black	Right and left thighs.
G/A3	I orange	I light blue	Right mid-axillary line on the same horizontal level as C and D.
I/A1	H orange	H light blue	Neck, avoid carotid artery and jugular vein.
J/A4	M orange	M light blue	Center of spine on the same horizontal level as C and D.

NEHB Lead Electrode Placement

For acquisition of the NEHB leads electrodes A/A1 and B/A2 must be applied in addition to the standard lead electrodes (C equals V4/C4).



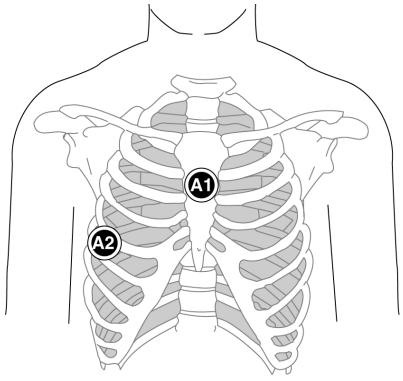
	AHA Label	IEC Label	Electrode Placement
A/A1	A1 orange	Nst white	Attachment point of 2nd rib to right sternal edge.
B/A2	A2 orange	Nax white	Fifth intercostal space on the left posterior axillary line. (Same position as V7/C7.)
C	V4 blue	Nap white (C4)	Mid-clavicular line in the fifth intercostal space. (Same position as V4/C4.)

Depending on the selected number of leads, the leads are recorded as follows (see "Modifying the Lead Sequence" on page 12-4 or "Modifying the Lead Sequence" on page 12-4).

Lead	12-Lead Monitoring	15-Lead Monitoring
D	channel 7	channel 13
A	channel 8	channel 14
J	channel 9	channel 15

CM5, CC5, ML (CML) Auxiliary Lead Electrode Placement

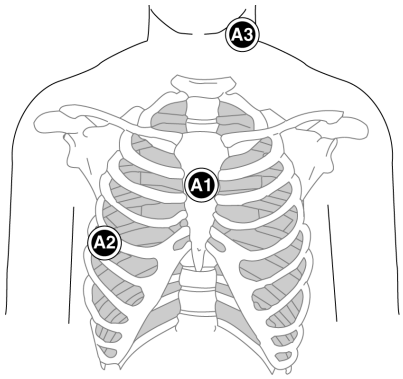
In addition to the standard electrodes, apply one electrode on the sternum (A1) and one in location V5R/C5R (A2).



Electrode	Electrode Placement
A1 (Nst)	Mid-sternum at the second intercostal space.
A2 (Nax)	In the fifth intercostal space in the right, anterior axillary line (V5F/ C5R).

CM5, CC5, CH (CMH) Auxiliary Lead Electrode Placement

In addition to the standard electrodes, apply one electrode on the sternum (A1), one in location V5R/C5R (A2) and one on the neck (A3).



Electrode	Electrode Placement
A1	Mid-sternum at the second intercostal space.
A2	In the fifth intercostal space in the right, anterior axillary line (V5F/ C5R).
A3	On either side of the neck or anywhere above the shoulders.

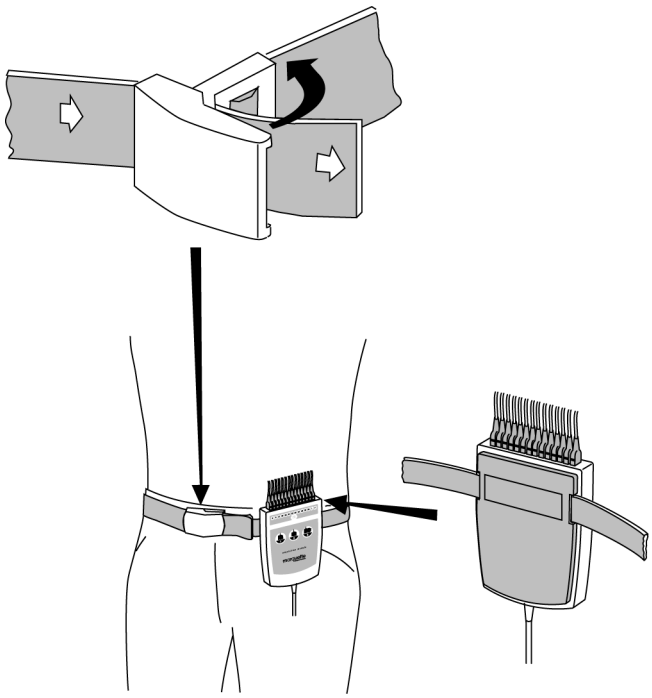
Attaching the Acquisition Module

If you are using a:

- CAM14 acquisition module, go to "CAM14" on page 3-12.
- CC14 acquisition module, go to "CAM CONNECT 14 (CC14)" on page 3-13.
- Wireless GEH-ECG 1200 acquisition module, go to "Attaching the Wireless GEH-ECG 1200" on page 3-15

CAM14

This section is applicable if you have upgraded the CardioSoft software to V7.0.



1. Attach the acquisition module to the patient.
2. Open the buckle to loosen the belt.

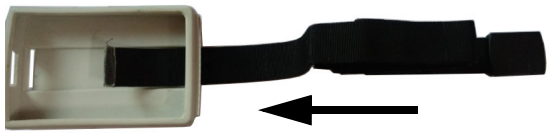
Following table describes the default configuration.

Button	Function (Resting ECG)	Function (Exercise Test)
Button 1 	Pressing this button initiates a 10-second resting ECG.	Pressing this button initiates a 12-lead report, if the default configuration is not changed.

Button	Function (Resting ECG)	Function (Exercise Test)
Button 2 	Pressing this button initiates a rhythm report.	
Button 3 	Pressing this button stops the writer.	

CAM CONNECT 14 (CC14)

1. Assemble the CC14 and the acquisition module holder.
   a. Ensure proper orientation of the lock and insert the belt into the one end of acquisition module holder slot as shown in figure.



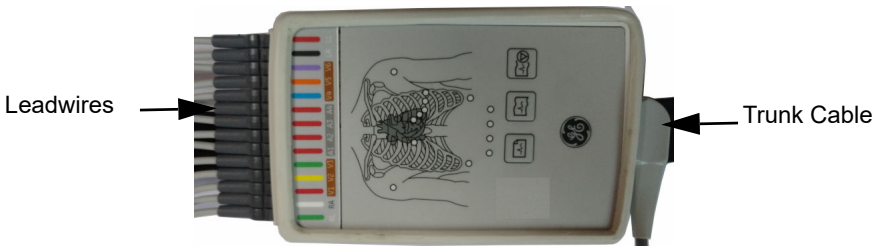
   b. Continue to insert the belt into cam holder till it comes out from the slot at the other end of acquisition module holder as shown in figure.



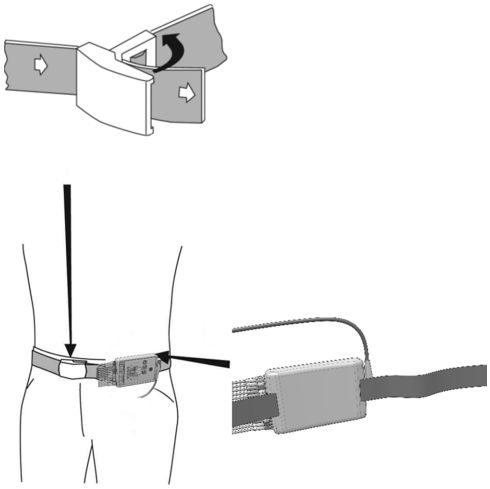
   c. Insert the CC14 into acquisition module holder.



   d. Connect the leadwires and trunk cable.



2. Attach the acquisition module to the patient.



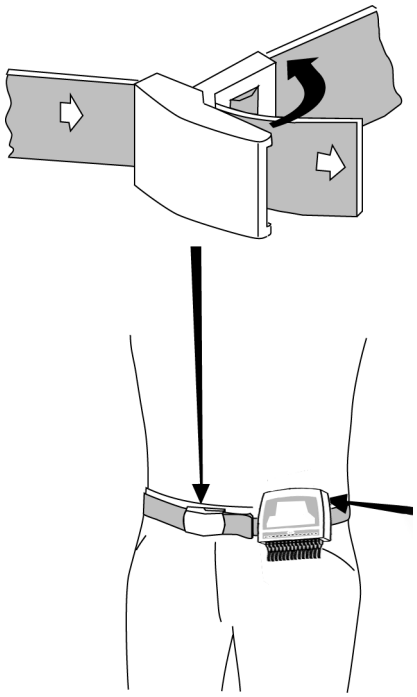
3. Open the buckle to loosen the belt.

For the CC14 acquisition module, the function of buttons vary with the test. For exercise tests, different tasks can be assigned to the buttons (see "Miscellaneous Tab" on page 12-26).

Following table describes the default configuration.

Button	Function (Resting ECG)	Function (Exercise Test)
Button 1 	Pressing this button initiates a 10-second resting ECG.	Pressing this button initiates a 12-lead report, if the default configuration is not changed.
Button 2 	Pressing this button initiates a rhythm report.	
Button 3 	Pressing this button stops the writer.	

Attaching the Wireless GEH-ECG 1200



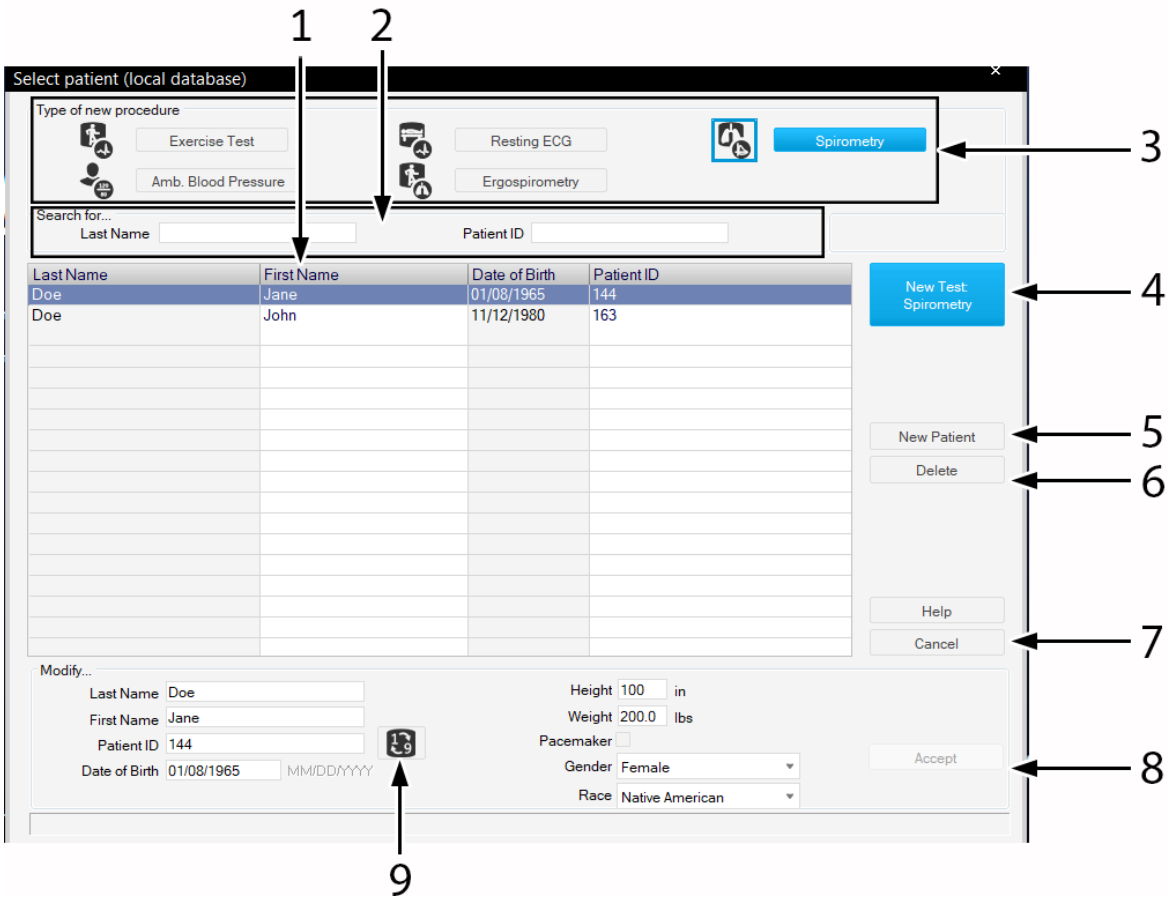
1. Attach the acquisition module to the patient.
2. Open the buckle to loosen the belt.

4 Selecting a Patient Record and Test Type

For your notes

Selecting a Patient Record from the Local Database

Overview



Note

Before running a new test, you are required to select a patient record from the database or to enter a new patient. Depending on the system configuration you will be working with the local database of the system or with the database of the MUSE system. When you select *New Test* on the initial screen, a window opens where you select the patient record and test type or enter a new patient.

1 The bar cursor highlights a patient record.

2 Text boxes for the patient's Last Name/Patient ID.

3 Option buttons for selection of the test type.

4 Click *New Test* to select the highlighted patient and go to the acquisition screen of the selected test type.

5 Click *New Patient* to activate the area for entry of patient information.

6 Click *Delete* to delete the highlighted patient record from the database.

7 Click *Cancel* to clear the window.

8 Click *Accept* to save the new or edited patient information to the database.

9 Area for entry of patient information.

Selecting a Patient Record

1. Enter the patient's last name or the patient ID to find a particular patient. It is sufficient to enter the first letters or numbers.

Note
As an alternative, you can select a patient by double-clicking the name from the list.

2. Select the test type.
3. Check the patient information. If it needs to be modified:
   a. Type over the current data.
   b. Click *Accept*.
4. Click *New Test* or press **Enter**. The acquisition screen for the new test will appear.

Entering a New Patient

1. Click *New Patient*.
2. Enter the patient's last name. Press the **Tab** key after each entry to move to the next text box.
3. Enter the patient's first name
4. Enter the Patient ID.
5. Enter the date of birth, height, and weight.
6. If your patient is wearing a pacemaker, select the *Pacemaker* check box.
7. Enter the patient's gender with 'm' or 'f'.
8. Click *Accept* to save the patient record to the database.
9. Select the test type.
10. Click *New Test*. The acquisition screen for the new test appears.

Retrieving a Patient Record from the MUSE System Database

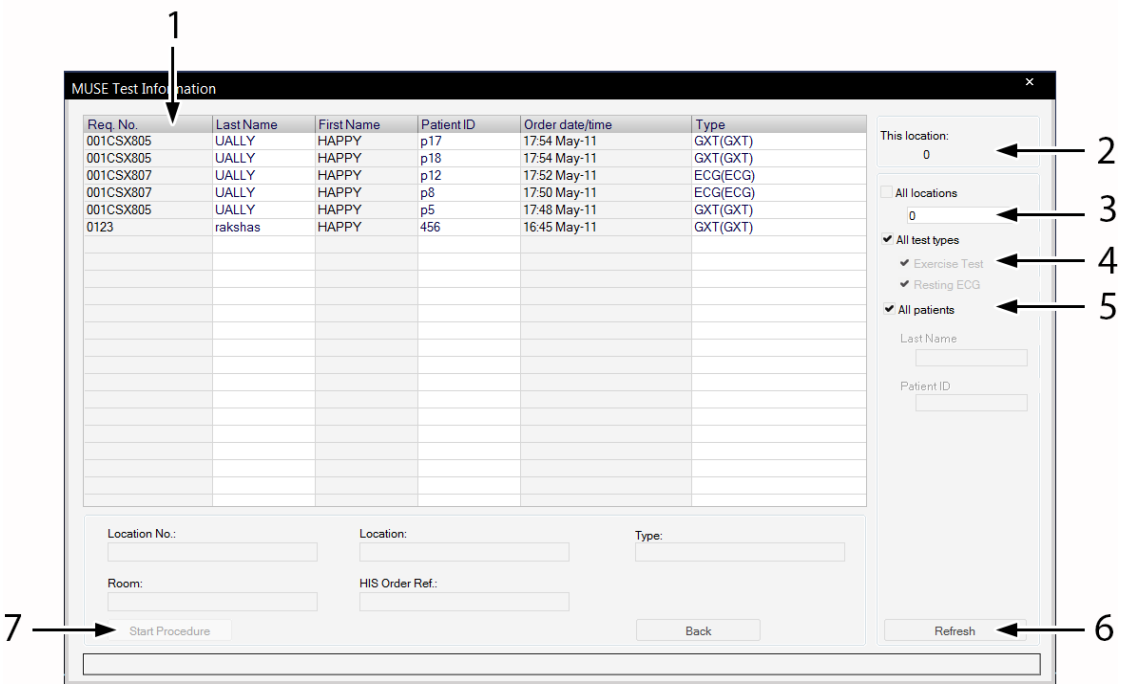
MUSE is an optional feature. When you click *New Test* on the initial screen, the patient selection window will appear. Patient record and test type are basically selected in the same way as from the local database.

The patient selection window has one additional button: *Order List* (see next page).

When you enter a new patient or edit patient information, the data is first saved to the local database. The data will appear in the MUSE system only after you have transferred the test to MUSE and confirmed the data there.

Orders from the MUSE System

The *Order List* lets you view a list of orders for the selected patient. If a patient was not selected, you will see the requested orders for all patients.



1 Requested orders.

2 Your location number.

3 The list only shows orders for your location.
The list shows orders for all locations.

4 The list only shows orders for the selected test type.
The list shows all orders.

5 The list only shows orders for the selected patient.
The list shows orders for all patients.

6 The list will be updated according to the current search criteria. After changing the search criteria, you can press the Enter key to start the search.

7 The test of the selected order will be started. If you do not change the search criteria, you can directly press the Enter key to start the search.

Patient Records of External Programs

The system supports the GE Healthcare Holter ECG program's MARS and CardioDay, as well as Spiro-SP's external spirometry test program EasyWare. We cannot guarantee full compatibility of external programs with CardioSoft.

With external programs, the patient record is always maintained in CardioSoft while the external program handles the test data. At the end of the test, CardioSoft will receive a summary from the external program and save this summary with the patient record.

Before selecting the external program, choose a patient in CardioSoft. To change the selected patient, you will have to exit the external program and select another patient in CardioSoft.

1. Start the CardioSoft Software.
2. Select the patient.
3. Select the external program on the procedure selection screen (the external program must already be configured).
4. Perform the procedure (for example a, Holter ECG).
5. Return to CardioSoft. The summary and recording is assigned to the patient record.

An external program can be activated only after it has been configured as described in section "Devices Tab" on page 12-42.

Note

When the configuration of external programs changes, maintain the compatibility to ensure that stored tests remain accessible.

5 Resting ECG

For your notes

Entering Test Information

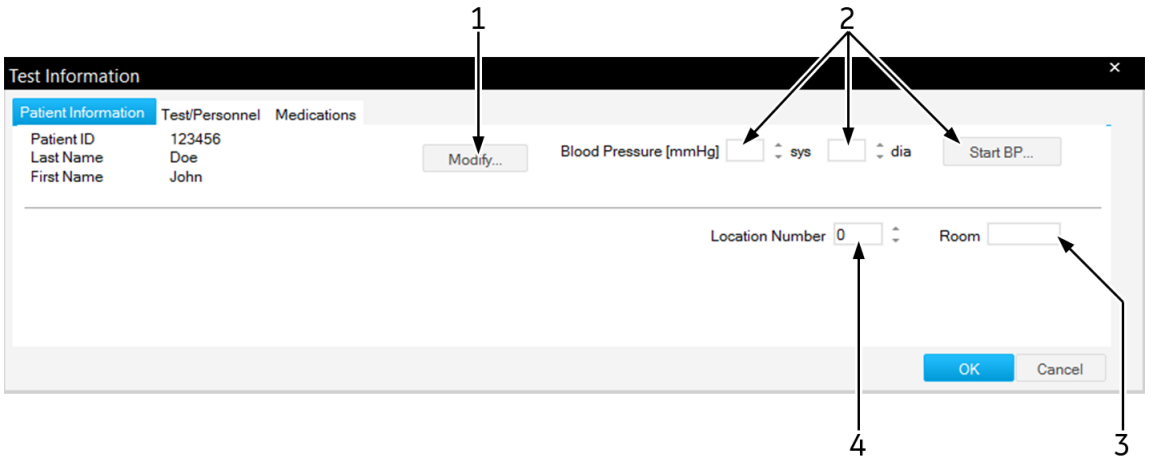
Overview

When you start a new ECG test, depending on your system configuration, the *Test Information* window will open automatically or you can display it with the *Test Information* button.

These are the tabs of the menu

- *Patient Information*
- *Test/Personnel*
- *Medications*

Closing a tab with *Cancel* or *OK* will open the acquisition screen.



Entering Patient Information

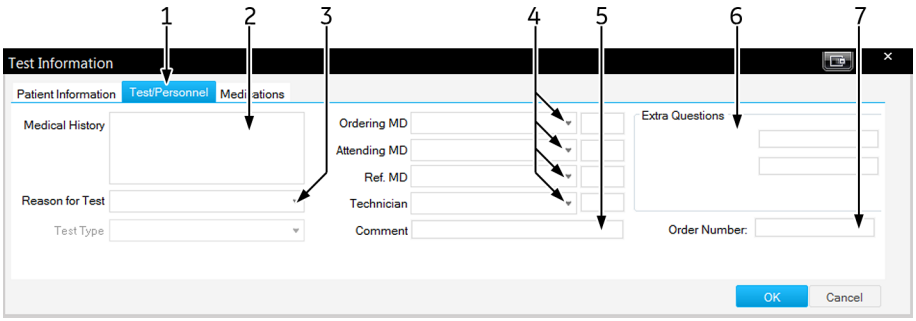
1. Verify the patient's name and ID. If the data is incorrect, click *Modify* to change.
2. Enter the blood pressure readings or initiate a blood pressure measurement with *Start BP...*.
3. Enter a designation for the Room (5 characters max.).
4. Select a *Location Number*.

Note

You can assign a Location Name to the Location Number (see section "MUSE Tab" on page 12-44).

The Patient Information can be assigned to the patient file or only to the pending test.

Entering Test/Personnel Information



1. Click *Test/Personnel*.
2. Type the relevant information in the *Medical History* field.
3. Enter the *Reason for Test* or select one from the list box. Multiple selections are permitted.
4. Type the physician's and technician's names or select them from the list boxes.
5. Type the *Comment* about the test.
6. Answer the *Extra Questions*.
7. Enter an Order Number. This number will appear on the printed reports and on the Test Summary.

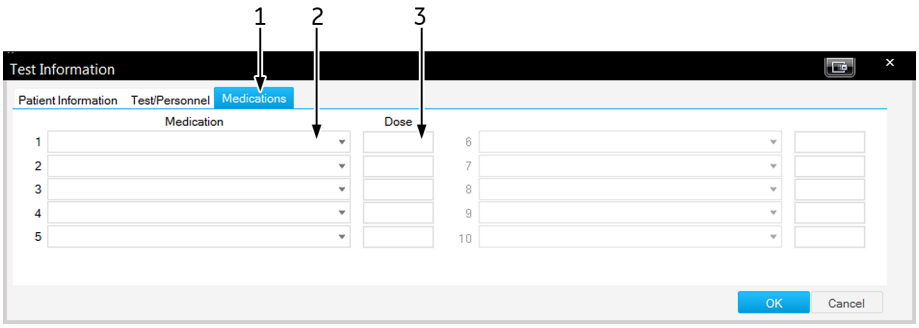
Note

The *Reason for Test* library can be edited (see section "Editing the Reason for Test Library" on page 12-3).

You can define two Extra Questions as needed (see section "Miscellaneous Tab" on page 12-22).

You enter the names of the physicians and of the ECG technician in the *System Configuration* menu (see section "General Tab" on page 12-35).

Entering Medications



1. Click *Medications*.
2. Enter or choose up to five medications.
3. Enter the dose.

Note

You can assign drugs to specific medication groups (see section "Editing Medication Groups, Assigning Drug Names" on page 12-4).

Entering a medication will influence the analysis with the HEART ECG analysis program. The following medications may affect the diagnosis:

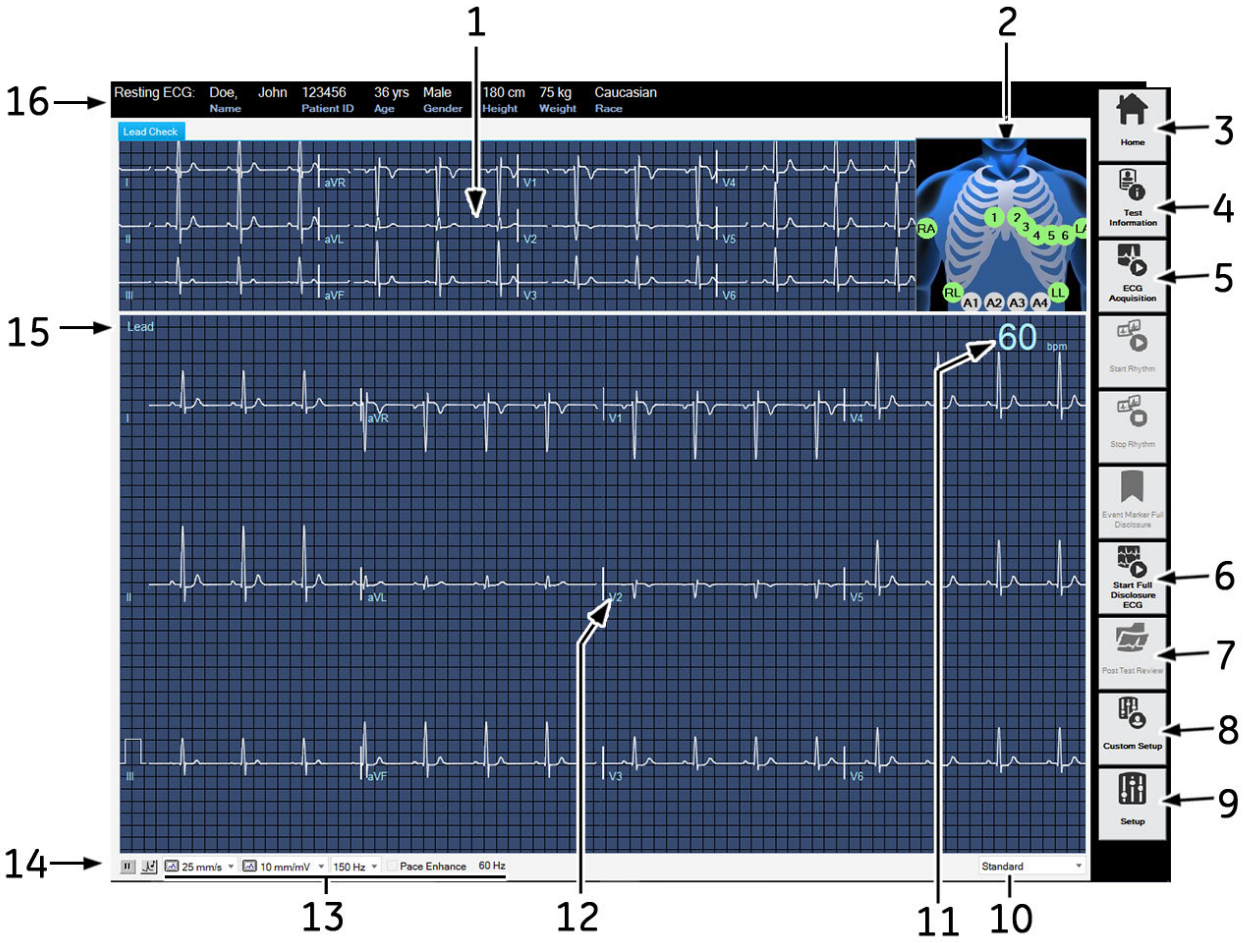
digitalis	antiarrhythmics Ic
diuretics	antiarrhythmics III
psychotropics	Ca channel antagonists Verapamil
steroids	Ca channel antagonists Nifedipin
beta-blockers II	nitrates
beta-blockers III	ACE
antiarrhythmics Ia	alpha-blockers
antiarrhythmics Ib	cytostatics

Recording a Resting ECG

Overview

In the upper part of the screen, the schematic representation displays the lead check information to verify the ECG signal quality. All 12 or 15 leads are shown. The schematic lead check torso allows you to verify the applied electrodes. The actual waveform data appears in the area below.

With this modality, you can acquire a 10-second resting ECG with subsequent analysis and/or you can record the full disclosure ECG for up to 60 minutes.



1 Lead check window

2 Graphic representation of the applied electrodes:
green: correct, yellow: lead problem (high impedance), white: not used, red: electrode disconnected or lead break (numbers indicate the impedance value in kilo-ohm).

3 Return to the Home screen.

4 Enter test information.
5 Start acquisition of the 10-second resting ECG.
6 Start acquisition of the full disclosure ECG.
7 End the test and display the report.
8 Load system setups stored for different system users (see section "Custom Setups, Factory Setup" on page 12-33).
9 Display the resting ECG setup menu (see section "Resting ECG Setup" on page 12-3).
10 Select a temporary lead sequence from the list.
11 Heart Rate.
12 Lead label: Right-click the label to display an up/down arrow for adjustment of the ECG baseline.
13 Status bar: controls for selection of speed/gain for writer and screen, low pass filter frequency (current ECG), indication of AC line filter, and ADS (if enabled).
14 Freeze and release the ECG waveforms (except lead at the top). Measurements can be performed on frozen waveforms (see "Measuring the ECG" on page 5-12).
15 Selection of a temporary screen format: click with the right mouse button to open the list, select a format with the left mouse button.
16 Display's Patient Information. Right-click on the patient information and select settings to edit the font size and style.

Note
when display settings are changed in application it is advised to restart the application.

Note
Filters limit the signal range and could suppress diagnostically relevant portions of the signal. Use filters only when it is necessary.

Conducting a 10-Second ECG with Analysis

The system continuously saves 10-second segments of the incoming ECG signal. When you select *ECG Acquisition* the most recent segment is stored and will overwrite a previous reference ECG.

1. Enter the *Test Information* or verify the data.
2. Click *ECG Acquisition* to initiate acquisition and analysis of the 10-second ECG.

The analyzed 10-second ECG appears at the top of the screen. A new tab provides the corresponding interpretation.

3. Check the 10-second ECG and data.
4. Optional: Select a different screen format.
5. Display the *Interpretation* and check the system evaluation and ECG measurement results.
7. Click *Post Test Review* to terminate signal acquisition and open the Test Summary.

Conducting a Full Disclosure ECG

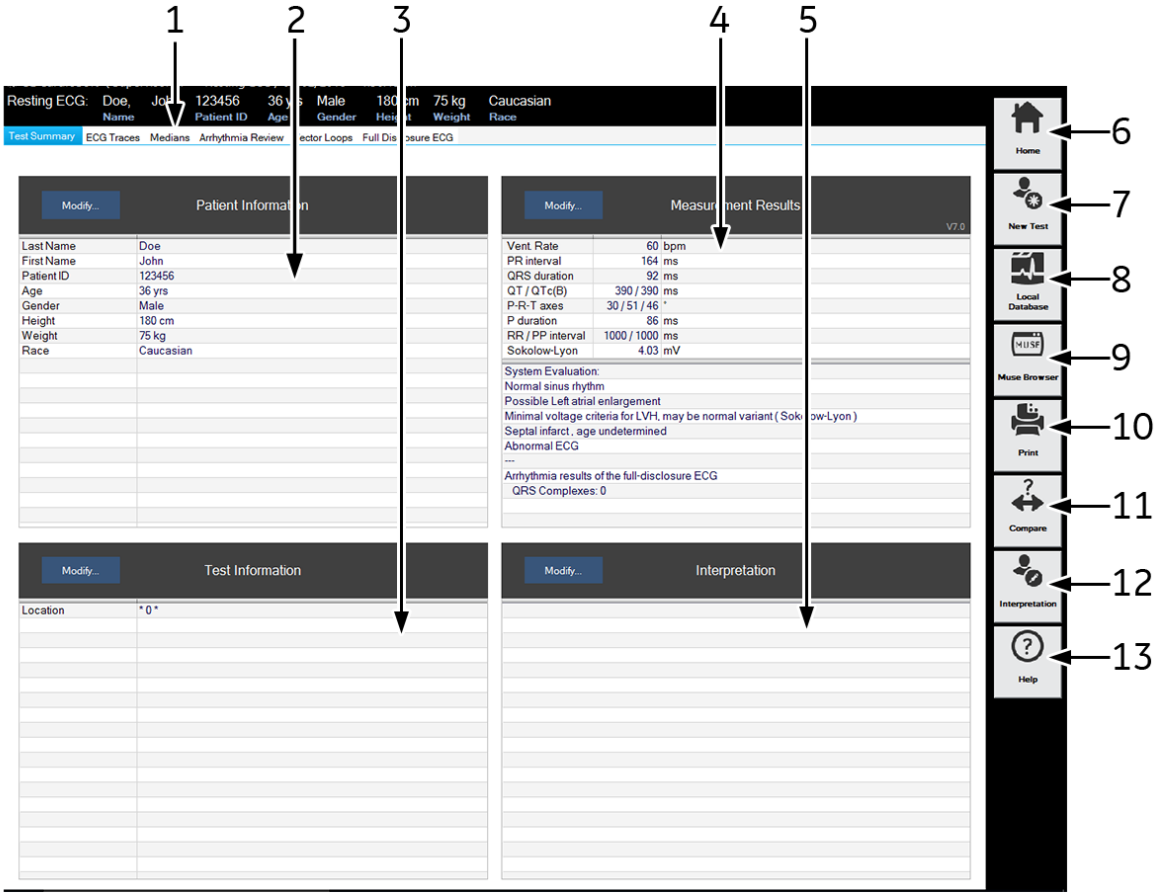
You can acquire the full disclosure ECG over a maximum period of 60 minutes.

1. Click *Start Full Disclosure ECG* to initiate ECG storage.
2. While the full disclosure ECG is acquired:
   - You can record an ECG acquisition.
   - You can click *Event Marker Full Disclosure* to enter event marks (vertical line).
   - The most recent arrhythmia is always displayed.
   - The remaining storage time, the total number of stored QRS complexes and the number or arrhythmic events is displayed.
3. Click *Stop FD/Post Test Review* to terminate the procedure and open the Test Summary screen.

Post Test Review

When the ECG acquisition is complete, you can click on *Post Test Review* to view the test results.

Test Summary



1 Tab selection.
2 Patient Information.
3 Test Information.
4 Measurement Results.
5 Interpretation area.
6 Return to the Home screen.
7 Display the patient list for a new test.
8 Display a list of tests of the current patient (local database).
9 Display a list of tests of the current patient (MUSE database system).
10 Open the print setup window.
11 Display a list of tests to compare with the current test.
12 Open the interpretation window where a detailed interpretation of the test can be generated.
13 Open Help.

The *Modify...* buttons allow you to edit or complete the data in the respective areas.

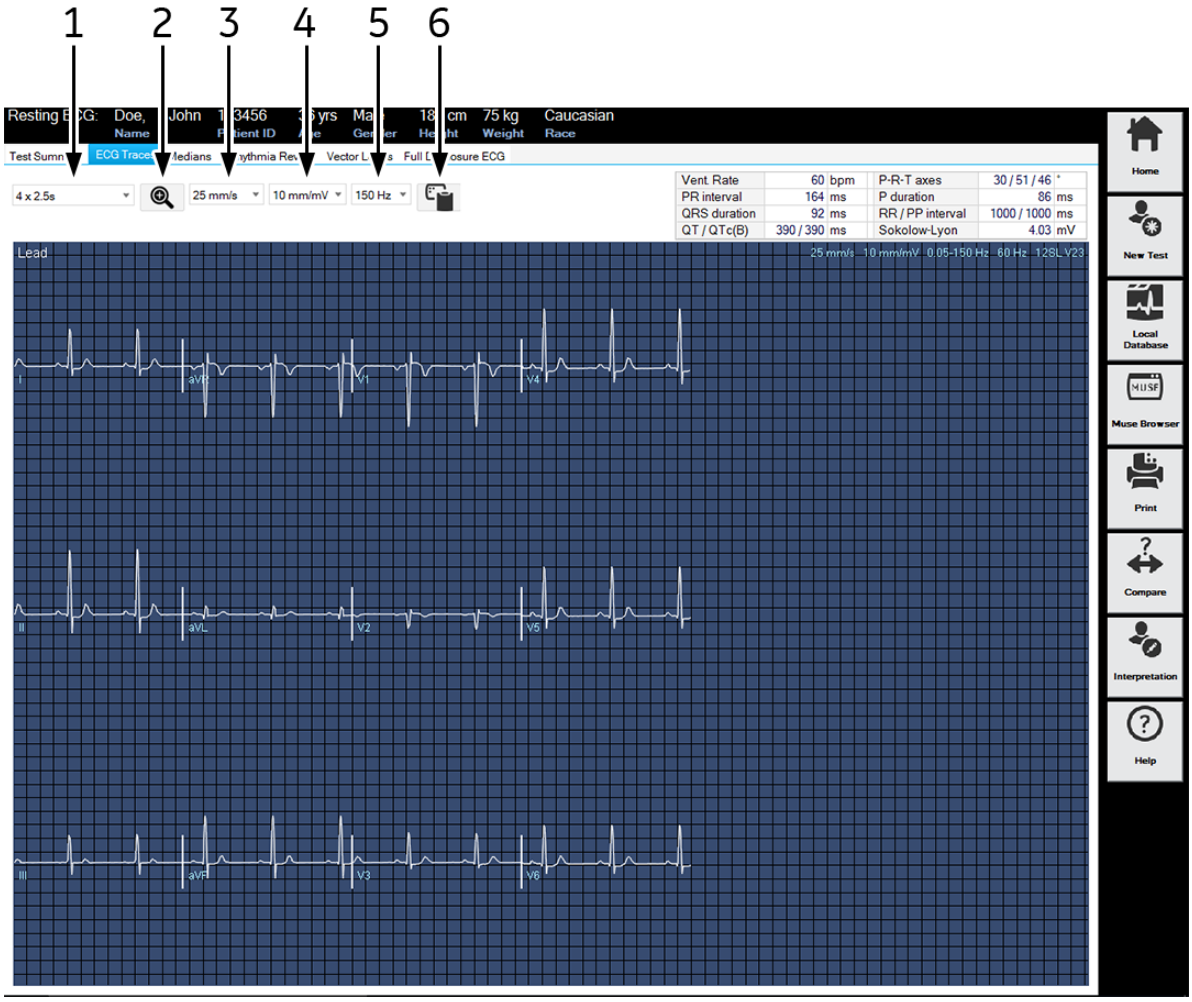
- *Patient Information*: The *Patient Information* window opens.
- *Test Information*: The *Test Information* window opens.
- *Measurement Results*: A window opens where you can edit the measurement results. Edited measurement results are identified with the * symbol. In the same window you can select ☑ and deselect the *View system evaluation* feature. This feature also affects the printout, the combined report, the transfer to MUSE and data export.
- *Interpretation*: A window opens where you can generate the test interpretation (see section "Generating the Interpretation" on page 5-20).

Note

- If any critical values are detected in the patient test, the critical results are displayed in the Measurement Results section if configured to display in the System Settings.
- Changes to the patient information will only affect the current test; previous tests of the same patient remain unaffected.

ECG Traces

This screen displays the reference ECG. Depending on the selected screen format and speed, the waveforms may take up several screens.



1 Select the screen format:

2 Activate zoom.

3 Change the gain (amplitude).

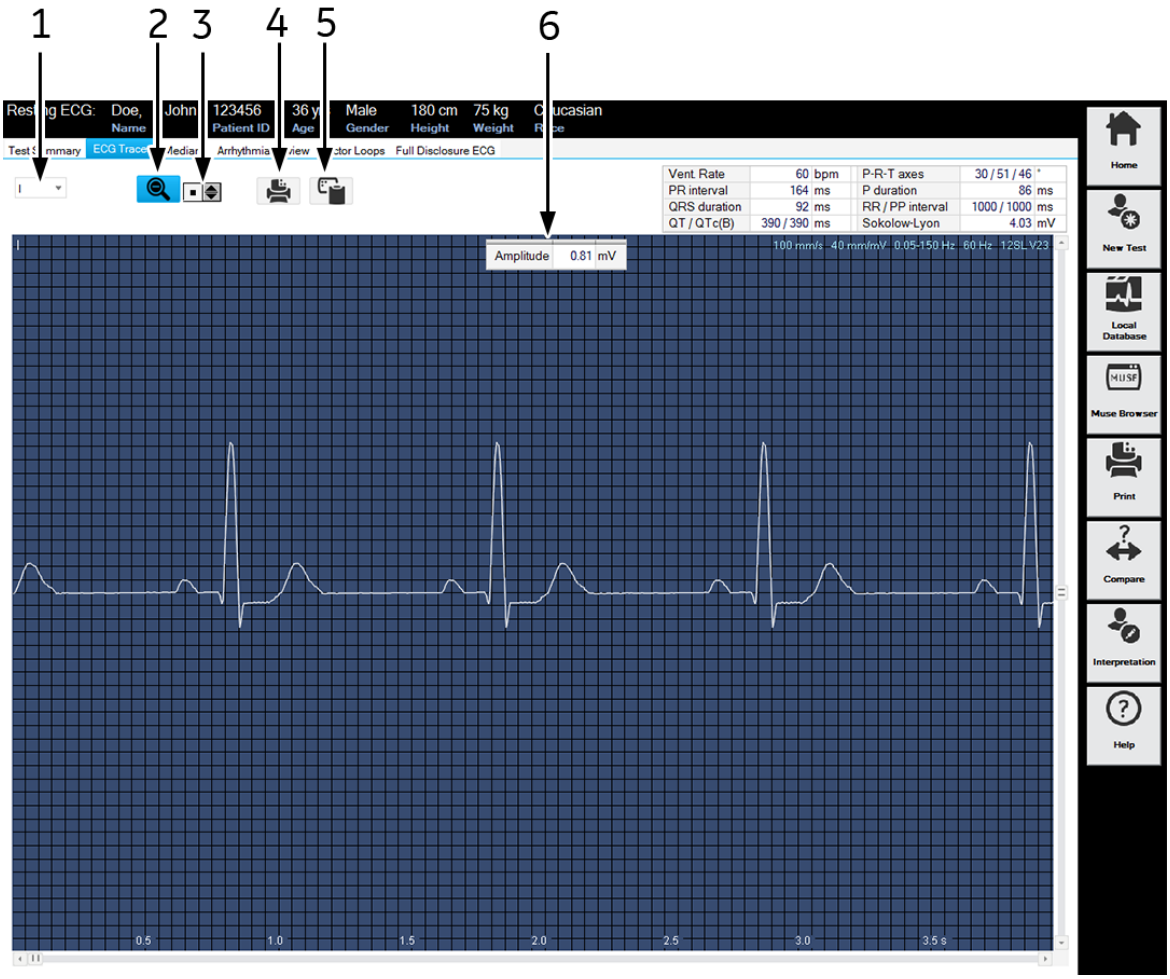
4 Change the speed.

5 Select the frequency for re-filtering the 10-second ECG.

6 Copy waveforms to the Clipboard. From the Clipboard the data can be inserted in another application, e.g. in Word, with the shortcut **Ctrl + V**.

Zoom Mode

You can select a zoom factor from two to 12 and the selected segment can be displayed in all leads.



1 Select the lead:
2 End zoom.
3 Select the zoom factor.
4 Print the segment.
5 Copy the segment to the Clipboard.
6 Cursor position in mV.

Measuring the ECG

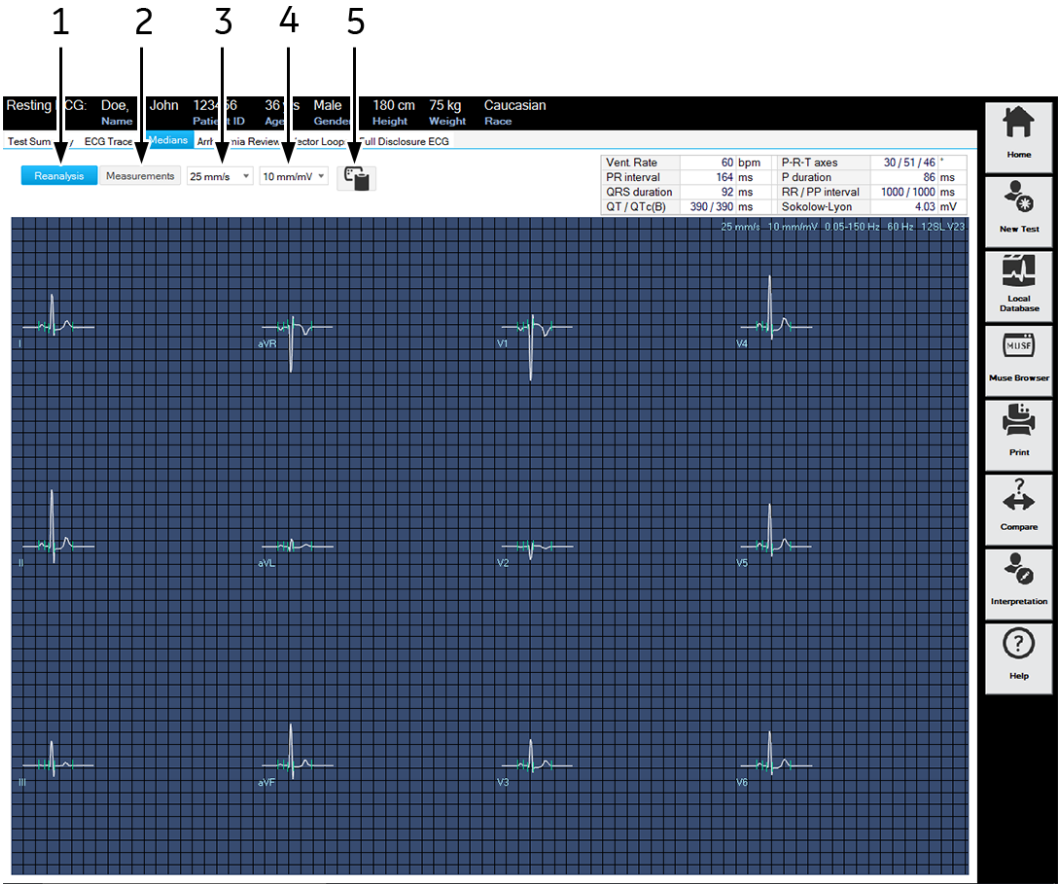
Amplitudes (mV), intervals (ms) and slopes (mV/s) can be measured on all ECG waveforms.

1. Position the cursor on the first measurement point and click. A caliper appears.

2. Position the cursor on the second measurement point and click to view a second caliper, measuring line, and the measurement results.
3. Right-click to remove measurement points.

Medians

This screen shows the median complexes of all leads as well as the measurement marks that formed the basis for analysis. You can make additional measurements.



1	Run a reanalysis.
2	Display the tabular summary.
3	Select the gain (amplitude).
4	Select the speed.
5	Copy the waveform to the Clipboard.

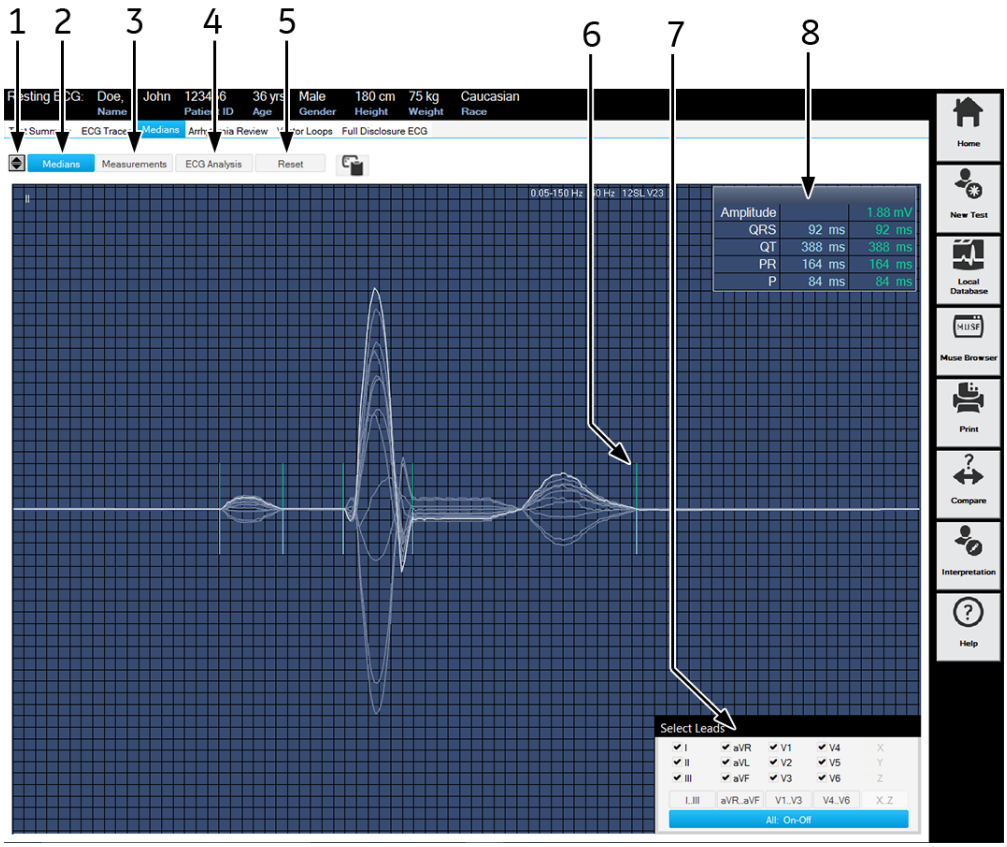
Reanalysis

Reanalysis allows you to change the position of the ST measurement marks. The reanalysis can only be performed on ECGs analyzed with the HEART program (see section “Miscellaneous Tab” on page 12-22).

On the reanalysis screen the medians of all leads are superimposed. The currently selected lead is highlighted. The measurement marks determined by the program are shown below the ECG baseline. The measurement marks above the baseline can be edited. The table in the top right-hand corner indicates the time intervals.

The T-offset measurement mark can be adjusted in each individual lead (see page after next).

Measurements can also be performed on the complex.



1 Select the lead.

2 Display the medians window.

3 Display the tabular summary.

4 Perform the reanalysis.

5 Reset the measurement marks to their original positions.

6 Measurement mark.

7 Menu for selection of the leads to be displayed.

8 Table showing time intervals and position of the cursor in mV.

Performing Reanalysis

1. Click the measurement mark and hold the mouse button depressed.
2. Move the measurement mark to its new position and release the mouse button.
3. Adjust the other marks in the same way.
4. Click *ECG Analysis*.
5. Click *Reset* and *ECG Analysis* if you wish to restore the previous analysis results.

Note

The P-onset and P-offset markers may be dashed, e.g. in the presence of atrial fibrillation. This indicates that the program was unable to locate the exact beginning and end of the P wave. In this case you can click the marks and drag them to the correct position; the marks are now solid instead of dashed. Restore the marks to the original position by clicking them again.

Adjusting the T-offset Mark

1. Select the check box.

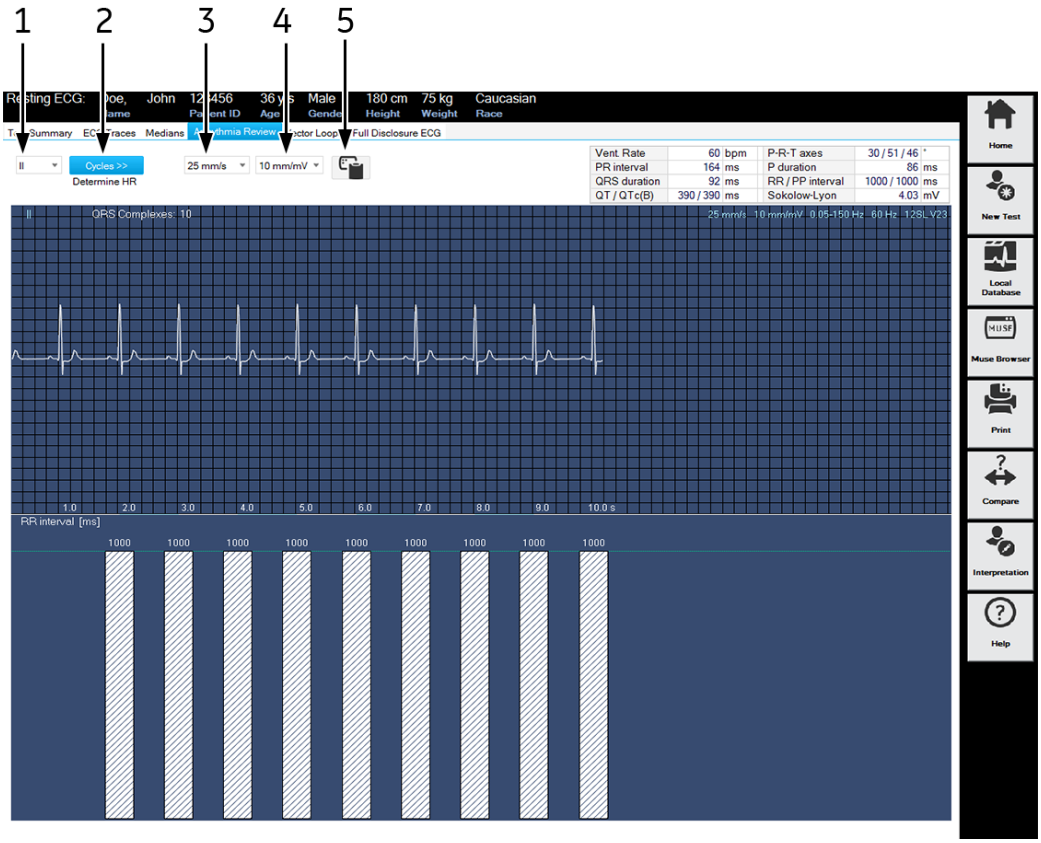
   The medians of all leads, except the selected lead, disappear.
2. Drag the T-offset mark to the correct position.
3. Click icon to select the leads whose T-offset marks you also wish to adjust.

   Adjusting the T-offset mark on this screen does not affect the position of the T-offset mark on the previous screen.

Arrhythmia Review

This screen displays one lead of the reference ECG. A bar diagram below the signal trace indicates, for each individual QRS complex, the deviation of the RR interval from the mean RR interval.

You can determine the HR over a selectable ECG segment.



1 Select the lead:

2 The number of cardiac cycles for atrial fibrillation or flutter, only.

3 Select the gain (amplitude).

4 Select the speed.

5 Copy the waveform area to the Clipboard.

Determining the Heart Rate

In a normal ECG:

1. Select the ECG to mark the beginning of the interval to be measured. A marker appears.
2. Select the end of the interval. A line appears connecting the two end points and the corresponding heart rate is displayed.
3. Right-click to remove the markers and data.

In the presence of atrial fibrillation or flutter:

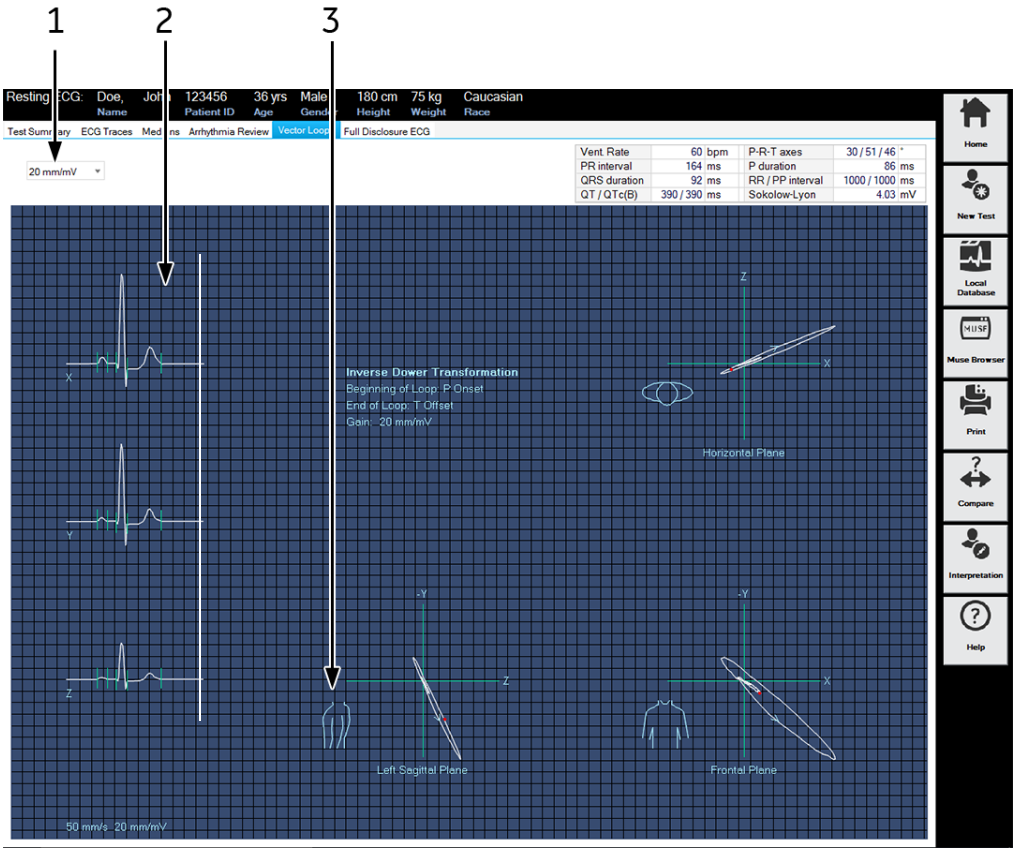
You will have to define a cardiac cycle yourself.

1. Click *Cycles* and select the number of cycles over which the HR is to be determined.

2. Select the ECG to mark the beginning of the interval to be measured. A marker appears.
3. Count the number of cardiac cycles and click again. A line appears connecting the two end points and the corresponding heart rate is displayed.

Vector Loops

This screen displays the median complexes of the orthogonal FRANK leads X, Y and Z as well as the vector loops in three planes.



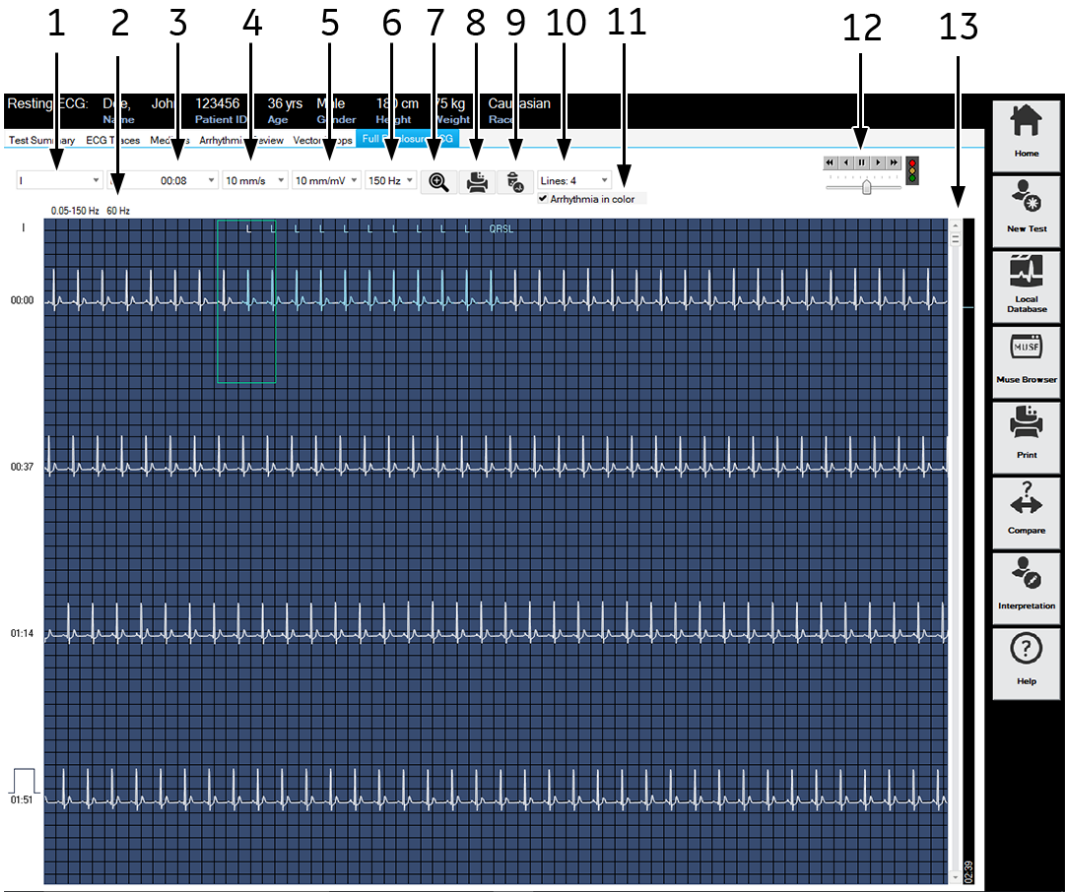
1 Adjust the gain.

2 Median complex.

3 Toggle between right and left sagittal planes.

Full Disclosure ECG

The Full Disclosure ECG screen displays one lead of the full disclosure ECG. The events identified by the rhythm analysis algorithm are color-coded.



1. Select the lead.
2. Information about filters, etc.
3. Listing of arrhythmias.
4. Select gain.
5. Select speed
6. Select frequency for re-filtering the 10-second ECG.
7. Click icon to activate the zoom function.
8. Print the full disclosure ECG or selected segments.
9. Delete the full disclosure ECG.
10. Select the number of lines and the event's color-coding.
11. Show arrhythmia in color.
12. Automatic scrolling of the ECG waveform, adjust the scroll speed with the slider below.
13. Scroll bar.

Printing the Full Disclosure ECG

You can print the entire full disclosure ECG or a selected segment.

1. Select the segment that you want to print.
2. Click the printer icon to open the print setup window.
3. Select the paper speed.
4. Click Format-1 option to print only one lead.
5. Select the lead.
6. Click Format-2 option to print multiple leads, and select the leads.
7. Click *Save* to save the print setup.
8. Start the printout or close the window with *Cancel*.

Enabling the Zoom Mode

1. Click the zoom icon.
2. Position the magnifying glass on the region of interest and click.

Analyzing Full Disclosure ECG Segments, Save as Resting ECGs

You can select a segment in the full disclosure ECG and save this segment as an additional resting ECG in the procedure list.

1. Click the zoom icon.
2. Position the magnifying glass on the region of interest and click.
3. Click  : 10 s of the selected segment to display the larger scale.
4. Select Yes in the dialog box to save the segment as a separate resting ECG.

Report Printout

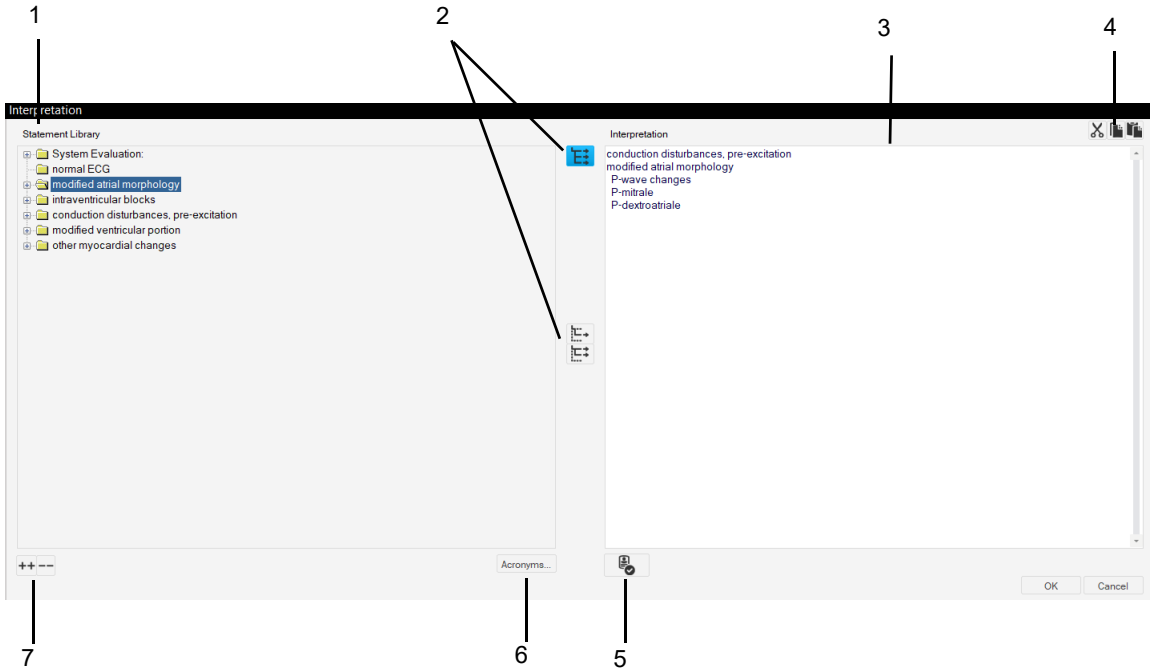
Click *Print* to print the report. The print setup window opens where you can temporarily adjust the settings for the printout. Refer to section "Run the Final Report" on page 12-6 for details on changing the setup permanently.

1. Select the documents to be included in the report:
   - *Configured Report.*
   - 10-second ECG (up to 3 different formats, with or without *Interpretation* or *ACI-TIPI score*).
   - Two more formats of the 10-second ECG.
   - *Medians.*
   - *Vector Loops*.

2. Select the lead format for the 10-second ECG.
3. Select the number of copies to print.
4. Choose the leads if you selected the Swedish *Median H1* format.
5. Select the rhythm leads.
6. Select whether or not the *Median H1* report is to include the measurement marks.
7. Select the gain.
8. Select the printer.
9. Click *Print*.

Generating the Interpretation

Click *Interpretation/Modify* to open the window. In the left part of the window you see a number of folders with standard interpretation text. With the *Acronyms...* button you can open an acronym window. The actual interpretation is generated in the right part of the window. The system generated evaluation is already shown. The system supports the creation of an interpretation by providing standard text and acronyms which can be copied to the Interpretation area on the right. In the Interpretation area you can edit the text as needed (enter new text, copy, remove, etc.). Refer to section "Editing the Interpretation Library" on page 12-4 for information on editing the standard text.



1 Open folders individually.

2 Copy folders, individual lines, lines including the chapter.

3 Cut, copy and paste text in the Interpretation area.

4 Resize or move the window.
5 Confirm the test results.
6 Open a window with acronyms and the corresponding diagnostic findings.
7 Simultaneously open (++) or close (- -) all folders.

Copying Diagnostic Statements Using Acronyms

1. Click *Acronyms...* to open the window.
2. Type the acronym.
3. Click *Insert>>* to copy the corresponding full text to the Interpretation.
4. Select the check box if you wish to copy each text to a new line.

Note
Interpretative statements transferred to MUSE that are part of the acronym list will be replaced with the appropriate acronyms.

Comparing Resting ECGs

You can compare the following details of two resting ECGs:

- 10-second ECG
- median complexes
- interpretation

You can also compare the medians of three to six ECGs.

Comparing Two Resting ECGs

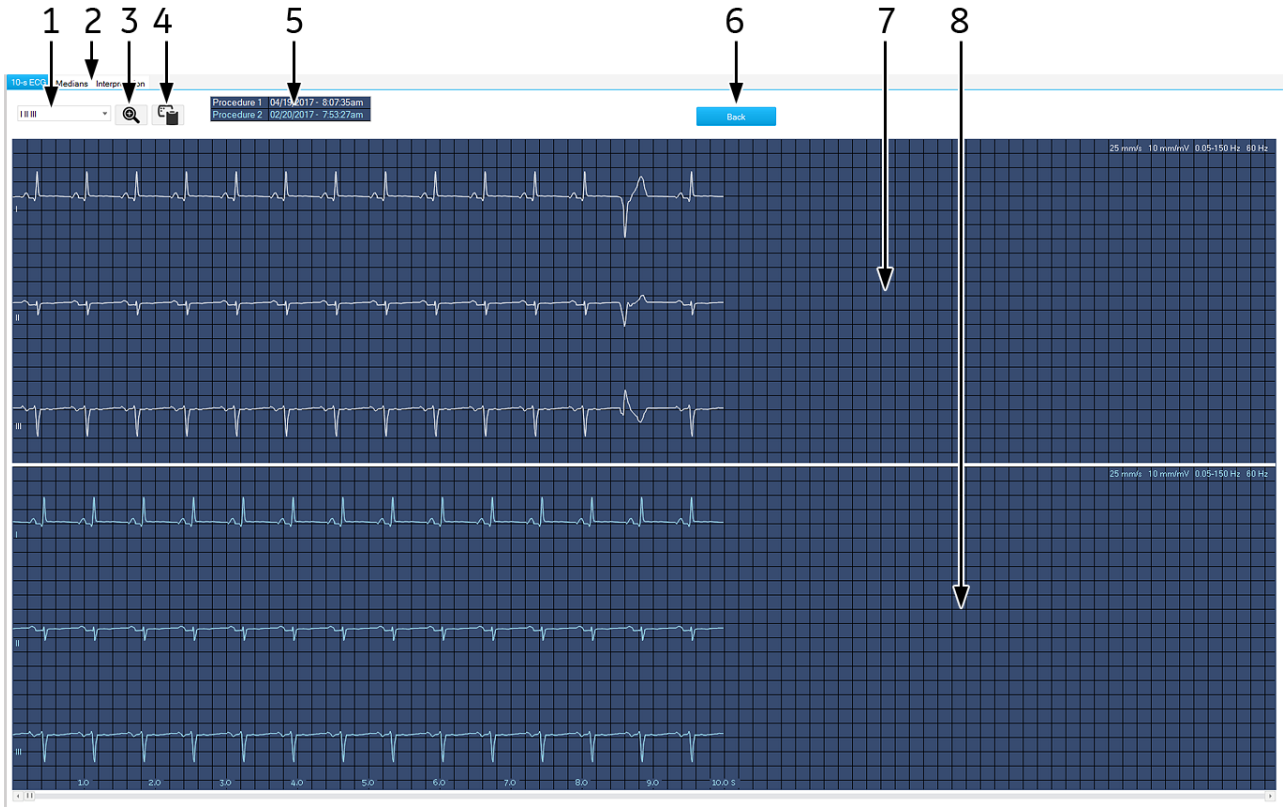
You can compare the present ECG with an earlier recording or you can retrieve a stored examination, as described in section "Selecting Patient Records" on page 9-3, and compare it with a second ECG.

1. Click *Compare*.

   A window opens listing all the patient's resting ECGs.
2. Select an ECG.
3. Click *OK* to clear the window.

   The comparison screen with the two 10-second ECGs opens.

10-Second ECG



1 Select the lead:
2 Tabs to compare the *Medians* and the *Interpretation*.
3 Activate zoom.
4 Copy the waveform area to the Clipboard.
5 Acquisition date and time.
6 Back button.
7 Procedure 1.
8 Procedure 2.

Medians

The *Medians* tab displays the screen for comparison of the two median complexes.

Interpretation

The *Interpretation* tab displays the screen for comparison of the two interpretations.

The following details of the two procedures are displayed:

- measurement results
- system evaluation
- the interpretation

Comparing Median Complexes from Multiple Resting ECGs

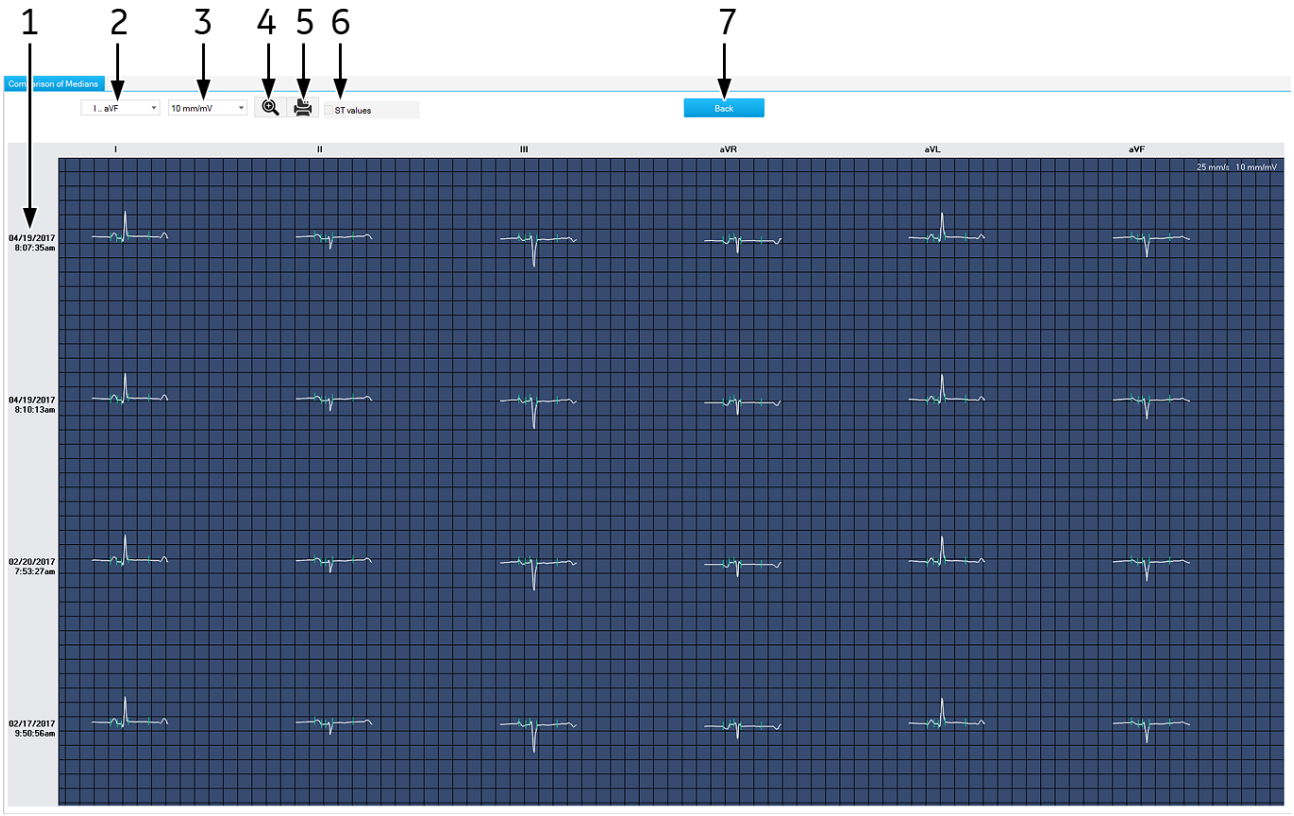
If you have the ECGH option, you can compare the medians of three to six ECGs.

1. Click *Compare*.

   A window opens listing all the patient's resting ECGs.

2. Hold **Shift** and, select the procedures.
3. Click *OK* to clear the window.

The comparison screen with the medians of the selected procedures opens..

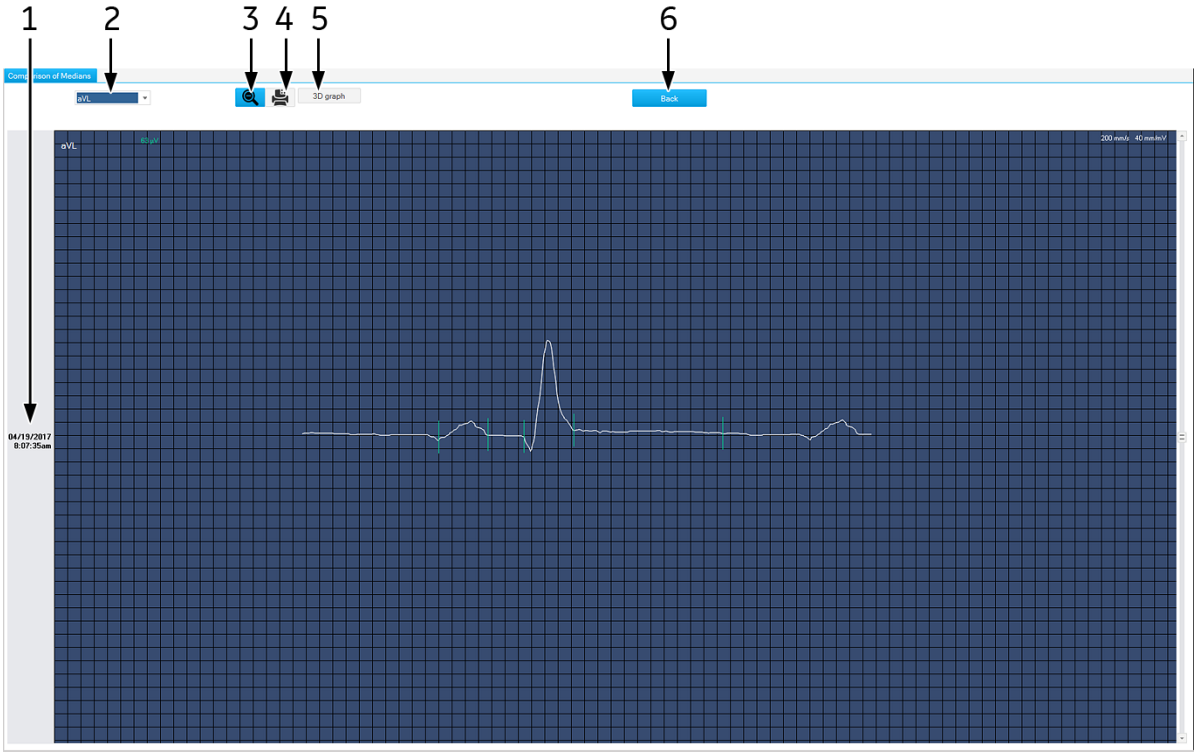


1	Acquisition date.
2	Select the gain.
3	Select the leads.
4	Activate the zoom function.
5	Print the screen.
6	Select and deselect the ST values.
7	Back button.

Zoom Mode

1. Click the zoom icon.
2. Position the magnifying glass on the region of interest and click.

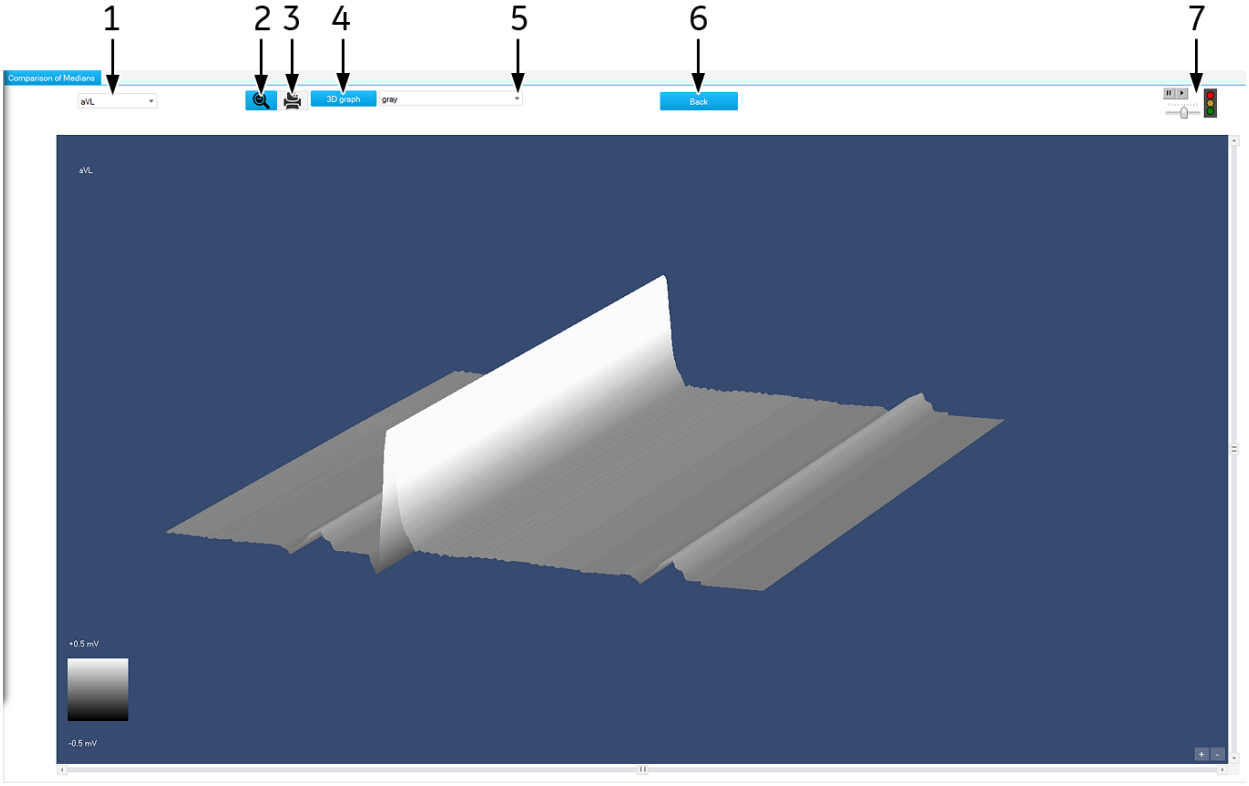
The selected median is displayed at a larger scale.



1	Acquisition date.
2	Select the lead.
3	Quit zoom.
4	Print the median.
5	Display the 3D graph.
6	Back button.

3D Graph

Click *3D graph* to display a three-dimensional representation of the medians.



1 Select the lead.

2 Quit zoom.

3 Print the graph.

4 Toggle 3D or 2D graph.

5 Select color.

6 Back button.

7 Start and stop the continuous rotation of the illustration; set the speed with the slider below.

6 Exercise Test

For your notes

Patient Education

Before the test you should give your patient some information about what will happen in the course of the test. Click the *Patient Education* button on the pre-acquisition screen to display a description of what the patient can expect to happen before, during, and after the exercise test.

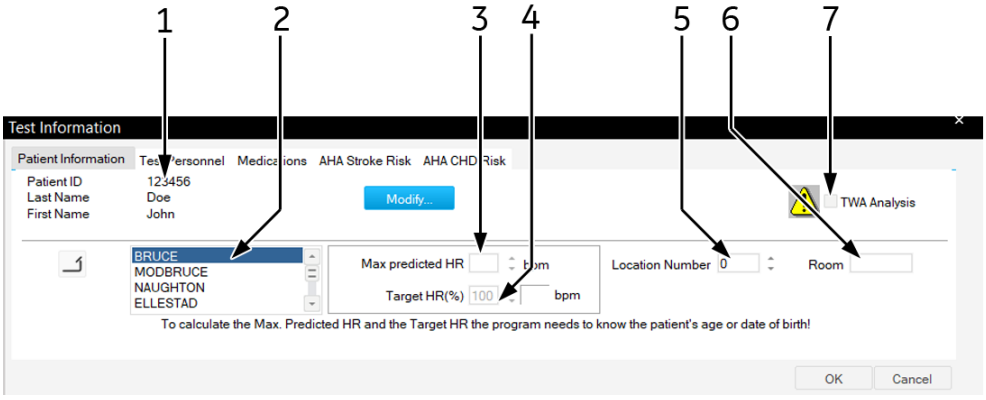
Entering Test Information

Depending on your system configuration, the *Test Information* window will open automatically or you can display it with the *Test Information* button.

These are the tabs of the menu

- *Patient Information*
- *Test/Personnel*
- *Medications*
- *AHA Stroke Risk*
- *AHA CHD Risk*

Closing a tab with *Cancel* or *OK* will bring up the acquisition screen.



Entering Patient Information

1. Verify the patient's name and ID. If the data is incorrect, click *Modify* to change.
2. Select the protocol for the next test.
3. Confirm or change the *Max. predicted HR* for the exercise test.
4. Enter the *Target HR (%)* of the *Max. predicted HR*.
5. Enter a designation for the *Room* (5 characters max.).
6. Select a *Location Number* or a *Location Name*.

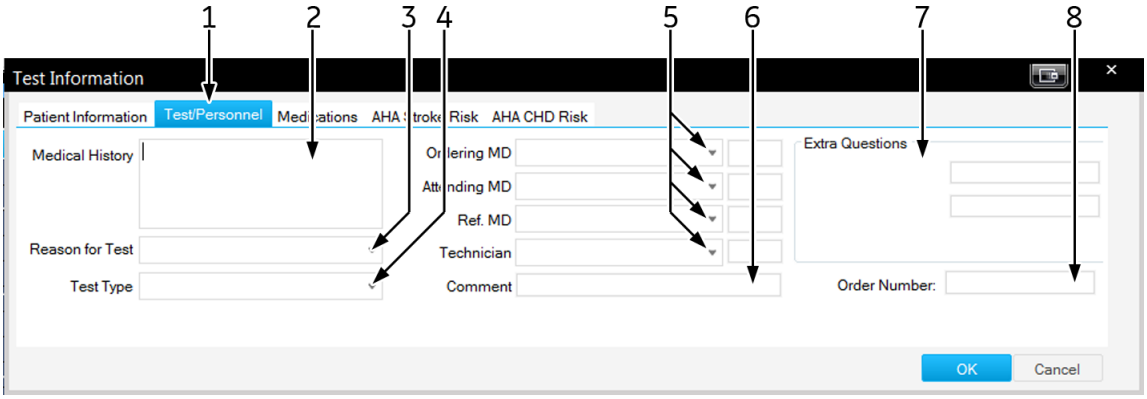
7. Enable or disable TWA analysis.

Note

The Patient Information can be assigned to the patient file or only to the pending test.

Before initiating TWA analysis check that all TWA settings are correct (see "TWA Tab" on page 12-18) and that the electrodes are properly applied according to the instructions given in chapter "Preparing the Patient" on page 3-1.

Test/Personnel Tab



1. Click *Test/Personnel*.
2. Type the relevant information in the *Medical History* field.
3. Enter the *Reason for Test* or select one from the list box. Multiple selections are permitted.
4. Select the *Test Type*.
5. Type the physicians' and technician's names or select them from the list boxes.
6. Type any comment about the test.
7. Answer the *Extra Questions*.
8. Enter an *Order Number*. This number will appear on the printed reports and on the Test Summary.

Note

The *Reason for Test* library can be edited (see section "Miscellaneous Tab" on page 12-26).

You can define two Extra Questions as needed (see section "Entering Extra Questions" on page 12-17).

You enter the names of the physicians and of the technician in the System Configuration (see section "General Tab" on page 12-35).

Entering Medications Information

1. Click *Medications*.
2. Enter or choose up to 10 medications.
3. Enter the medication dose.

Note

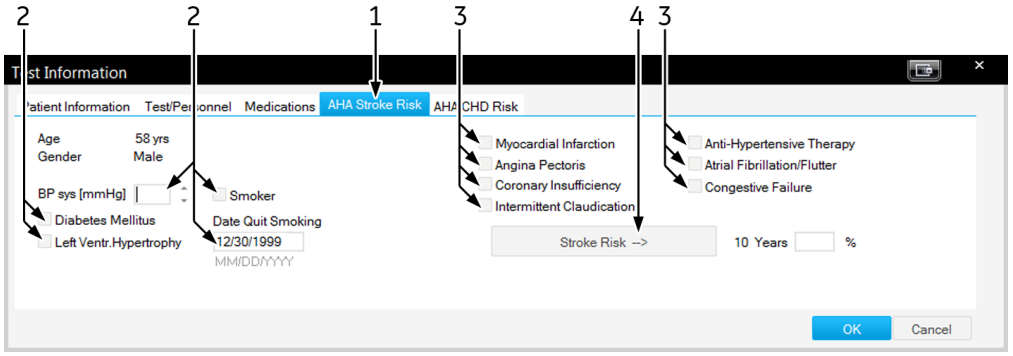
You can edit the libraries (see section "Editing the Comments, Test Types, Reason for Test, Reasons for Termination, Medications Library" on page 12-16).

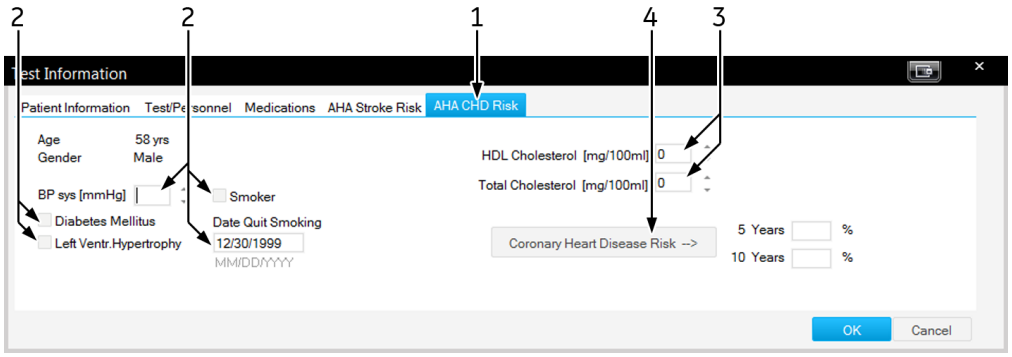
Calculating Patient Risk

To calculate the patient's risk for stroke and CHD you must enter the patient's age and gender. The system will assume some values for parameters that are unknown or out-of-range. Refer to "Risk Factors" on page B-9 for the table of values.

The risk calculations are a prediction of group incidence and may not apply to individual patients. Refer to the American Heart Association publication "Instructions for Using Coronary Risk and Stroke Prediction Charts and Worksheet" (1990) for details.

The system automates the manual calculation of risk. You can edit the values calculated by the system. Edited values are marked with an asteriks*.



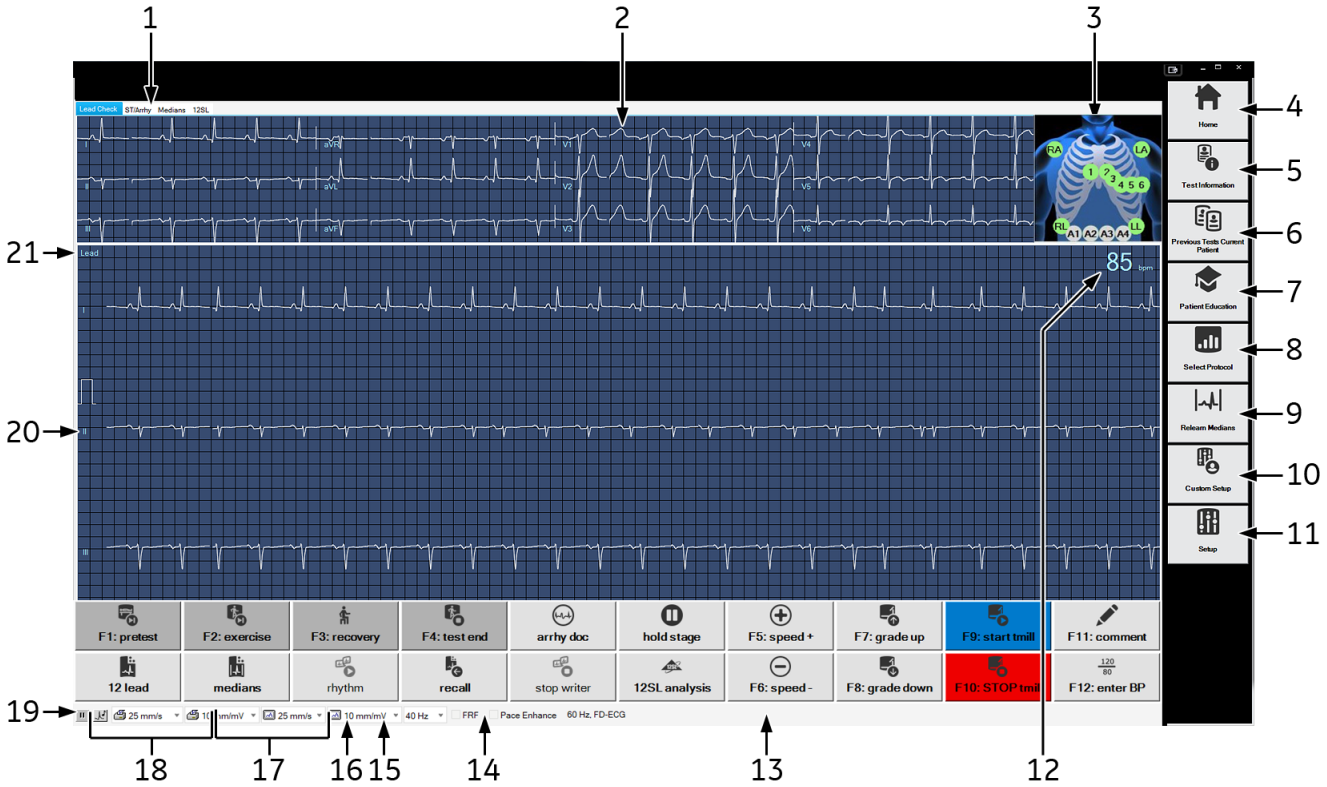


1. Click *AHA Stroke Risk* or *AHA CHD Risk*.
2. Enter the factors that influence both coronary and stroke risks.
3. Enter the factors that influence stroke or coronary risk.
4. Click *Stroke Risk* or *Coronary Heart Disease Risk*.

Before the Test

Pre-Acquisition Screen

In the upper part of the screen, you see the lead check information for verification of the ECG signal quality. All leads are shown. The schematic lead check torso allows you to verify the applied electrodes. The actual waveform data appears in the area below.



1 Tabs showing the different ECG analysis data.

2 Lead check status window.

3 Representation of the applied electrodes:
green: correct, yellow: lead problem (high impedance), white: not used, red: electrode disconnected or lead break (numbers indicate the impedance value in kΩ).

4 Return to main window..

5 Enter or review test information.
6 Select current patient's previous tests.
7 Display Patient Education.
8 Select an exercise test protocol. A new protocol will become effective in the next phase.
9 Relearn the median complex. With *Relearn Medians* you can also restart the learn phase when not all electrodes are applied.
10 Click to load system setups stored for different system users.
11 Click to edit the exercise test setup.
12 Heart rate.
13 Virtual keypad.
14 System messages.
15 Enable or disable FRF or ADS algorithm, see note below.
16 Filter frequency (current ECG).
17 Screen gain and speed.
18 Writer gain and speed (for ECG recordings in real-time only).
19 Freeze and release the ECG waveforms (except lead at the top).
20 Lead label, right-click to display an up/down arrow for adjustment of the ECG baseline.
20 Writer gain and speed (for ECG recordings in real-time only).
21 Change selected lead.

Note

Muscle filters (20 Hz, 40 Hz, 100 Hz) could also suppress diagnostically relevant portions of the signal, as they limit the signal range. Therefore, muscle filters should only be enabled if necessary.

ADS and FRF are algorithms that significantly reduce artifact and baseline fluctuations without adversely affecting the ECG signal as conventional filters do. Therefore, the system allows you to enable and disable the algorithms before or during the test, as needed.

During the exercise test, a new protocol selection with *Select Protocol* will become effective in the next phase.

Pacemaker Patients — You must indicate that the patient has a pacemaker.

We recommend that you use the FRF ON filter setting for exercise tests:

Starting the Test

Note

When the exercise test is performed for the first time on a Windows 10 operating system, an alert message "Windows Firewall has blocked some features of this app" is displayed. Click "Allow access" to avoid this alert message in the subsequent tests.

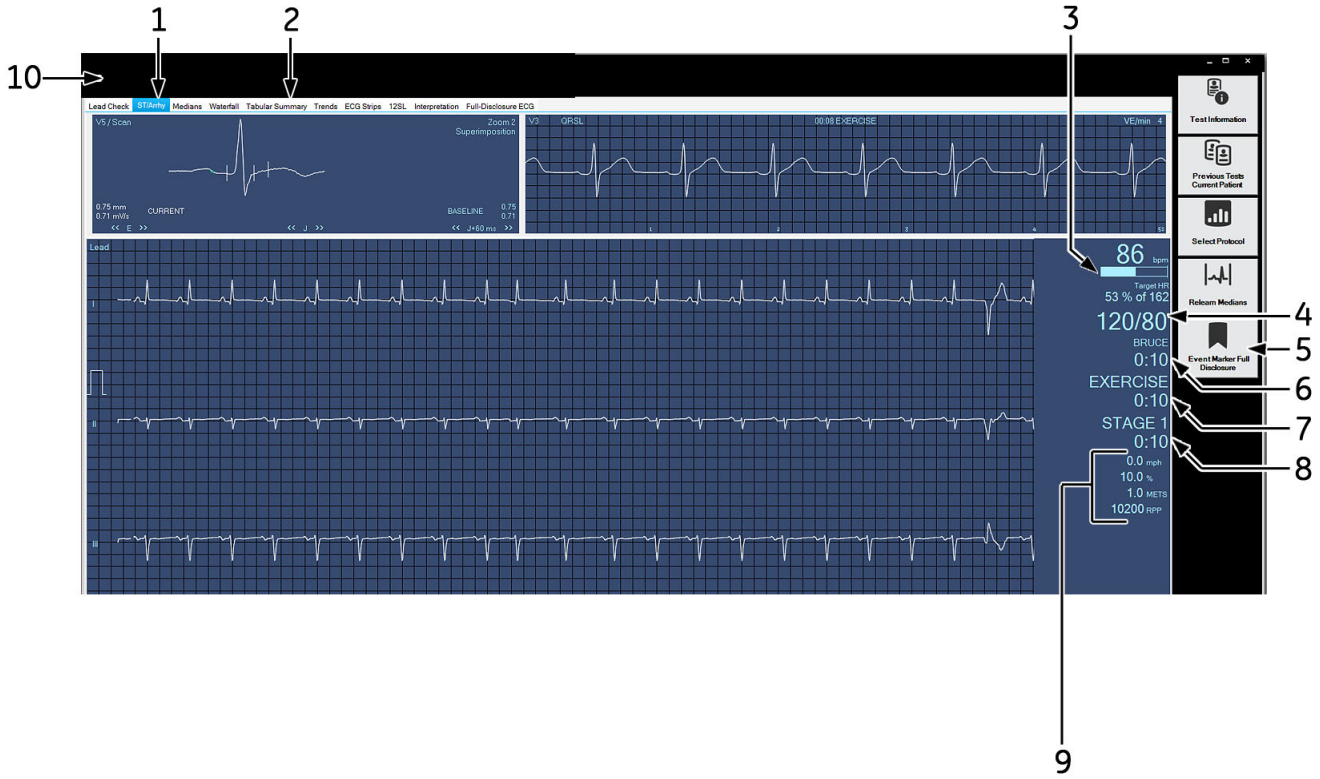
1. Check the applied electrodes and verify the signal quality in all leads. ST measurements and arrhythmia analysis will automatically be displayed when all necessary electrodes have been applied and signals of adequate quality are obtained (e.g. without major baseline fluctuations). If all electrodes are not being used, click *Relearn Medians* to manually activate ST measurement and arrhythmia analysis.
2. Click *Select Protocol* to verify that the appropriate test protocol is active or to select another protocol.
3. Click *Patient Education* to display the patient exercise test instructions.
4. Click *Custom Setup* to select and load user-specific test settings.
5. Click *Setup* to edit the exercise test setup.

Note

Once you initiate the pretest phase you can no longer change the test settings.

6. Press **pretest** to initiate the test. The pretest screen will appear and the pretest phase begins.

Acquisition Screen



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1 *ST/Arrhy* window (see section "ST/Arrhy" on page 6-12 for details).

2 Display windows with ECG test data (see "ST/Arrhy" on page 6-12 to "Interpretation" on page 6-17 for details).

3 Current heart rate and bar graph indicating percentage of max. predicted HR (see "Miscellaneous 1 Tab" on page 12-15 and illustrations below). Turns red when max. HR is exceeded.

4 Most recent BP readings. Turn red when max. systolic BP is exceeded. Values older than one minute are dimmed.

5 Mark and save ECG events (see section "Arrhythmia Review" on page 6-28).

6 Selected protocol, exercise clock - starts with the exercise phase and indicates its duration.

7 Current phase, phase clock - each new phase, resets the clock to zero.

8 Current stage, stage clock - restarts with each new stage.

9 Treadmill: belt speed and grade. For a treadmill, the values "**.*" for Speed and Grade indicate the treadmill cannot be controlled. Bicycle ergometer: pedal speed (RPM) and load METS (metabolic equivalents) see "METS Formula (Metabolic Equivalents)" on page 6-15 RPP (Rate Pressure Product).

10 Display's Patient Information. Right-click on the patient information and select settings to edit the font size and style.

Note

When display settings are changed in the application, it is advised to restart the application.

Pretest Phase

The pretest phase consists of stages configured in each protocol. Common stages are:

- Supine
- Standing
- Hyperventilation
- Warm-up

Blood pressure measurements can be taken manually or automatically as configured in the *Protocol Editor*. When manual entry is configured, the window for entry of BP values will appear automatically (see section "Protocol Editor Tab" on page 12-12).

The first QRS complex of the exercise phase is saved as the baseline complex.

Running a Pretest

1. Wait until the message *Median update ceased... Relearn* disappears, the baseline ST measurement appears and the blood pressure has been taken.

2. Press
   a. The **12 lead** button to initiate a recording on the printer
   b. The**12SL** button to acquire and analyze a baseline ECG
   c. The **medians** button to print a baseline ECG on the printer.
3. Press **pretest** to advance to the next stage.

Note
When the TWA algorithm is enabled, ensure that the pretest phase is long enough (approx. 1 minute for update factor of 1/8).

Exercise Phase

The selected protocol will control the treadmill or bicycle ergometer. When you enter the exercise phase:

- Belt speed and grade or the bicycle load will change according to the selected protocol
- Exercise clock will start (phase and stage clocks restart at zero), and
- System will start saving test data. This data can be viewed on the tabs at the top of the screen (see "ST/Arrhy" on page 6-12 to "Interpretation" on page 6-17).

Starting a Treadmill Test

The maximum speed supported by CardioSoft application for stress test using treadmill is 13.5mph (22kmph).

Treadmill

1. Press the **exercise** button to enter the exercise phase.
2. Press the **start treadmill** button to start the treadmill.

Warning
FALL HAZARD — Your patient should wait until the treadmill belt is moving before stepping onto the belt. Otherwise severe injury could result from a fall. For the same reason, avoid rapid changes in belt speed.

If a higher load level is selected manually before the treadmill is started with the **start tmill** button, the treadmill will accelerate to the speed corresponding to the manually selected load level.

For a FAST stop of the treadmill in an emergency, press the **STOP tmill** button and hold it down until the treadmill comes to a stop, or hit the emergency stop button on the treadmill. Note that when restarted after FAST stop, the treadmill returns to the previous speed

and grade.

Note

When the TWA algorithm is enabled, ensure that the patient does not run until the heart rate exceeds the TWA heart rate limit (default value: 125 BPM, see "TWA Tab" on page 12-18).

Bicycle

The exercise test starts automatically when the patient starts pedaling.

Manual Control

comment	Press to enter comments to appear in the *Tabular Summary*.
enter BP	Press to enter BP readings.
12 lead	Press to start an ECG recording (12 leads, 5 seconds from memory, 5 seconds of real-time data).
recall	Press to print a 10-second delayed recall report on the printer.
rhythm	Press to start a continuous rhythm report on the printer.
medians	Press to print a medians report.
arrhy doc	Press to enable or disable the automatic documentation of arrhythmias.

Note

ADS/FRF algorithms can delay the rhythm report by approximately 2 seconds when enabled.

12SL analysis	Press to acquire a 12SL resting ECG with measurements and interpretation (Pretest and Recovery phases only).
grade + **grade -**	Press to change the elevation of the treadmill belt.
speed w+ **speed w–**	Press to change the belt speed or ergometer load.
exercise	Press exercise to initiate the exercise phase and to advance through the individual stages of the exercise phase.
hold stage	Press to hold the exercise test in the current stage.
start tmill/ **STOP tmill**	Press to start and stop the treadmill belt.

Note

By pressing the exercise button within the exercise phase, you can advance to the next stage without switching to manual control.

In the pretest phase, **Shift +** *pretest* or **Shift + F1** allow you to return to the previous stage.

If a bicycle ergometer test is initiated with the **exercise** button, the clock will start even when the patient has not yet begun to pedal.

When the patient reaches the target HR, the HR reading turns red and an audio signal sounds (if configured, see section "Miscellaneous

1 Tab" on page 12-15).

Using the treadmill speed and grade buttons during a protocol puts the treadmill in manual control. The system is no longer controlled automatically by the protocol. The system will enter a new stage and the phase name appearing in the Tabular Summary will be *Manual*.

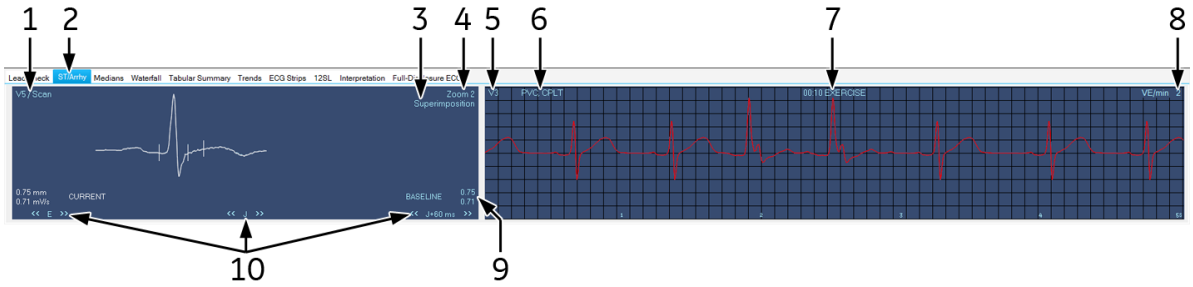
ECG Data Windows

ST/Arrhy

The *ST/Arrhy* window displays the median complex (left) and the current arrhythmias (right). As soon as the exercise phase begins, the current median complex is superimposed on the baseline complex and both measurements are displayed.

The system chooses the two leads with the greatest amplitude for arrhythmia analysis (click E to select another lead). The system starts saving arrhythmias at the beginning of the pretest (20 arrhythmias max., following preset priorities, see section "Arrhythmia Review" on page 6-28)

.



1 The lead label to display the median complexes of other leads. The message *Scan* indicates that the system has chosen the lead with the most significant ST depression. (Leads aVR, aVL, V1 are not considered.)

2 The *ST/Arrhy* window tab.

3 Click *Superimposition* to display the median complexes from all leads superimposed (click again to restore normal presentation).

4 Change the size of the median complex.

5 Open a window for manual selection of the arrhythmia lead (the system automatically selects the 2 leads with the greatest amplitudes).

6 Arrhythmia label.

7 Time at which arrhythmia occurred in the indicated phase.

8 Number of ventricular ectopics per minute.

9 ST measurements.

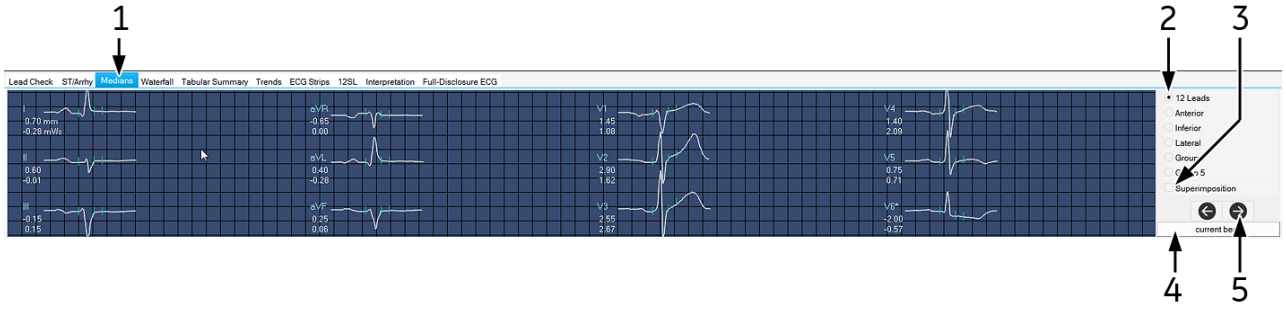
10 Adjust the E, J and J+x reference points (only in "manual" mode, see section "ST/Medians / 12SL Tab" on page 12-18).

Note

Significant arrhythmias are displayed with red waveforms.

Medians

The *Medians* window displays the current median complex. The system saves new median beats at the time intervals selected in the *Protocol Editor* (see section "Protocol Editor Tab" on page 12-12).



1 Click the tab to display the *Medians* window.

2 Click option button to select different lead groups (see "Screen Tab" on page 12-9 for information on how to assign the leads to the groups).

3 Click *Superimposition* to display the median complexes of the selected group superimposed (click again to restore normal presentation).

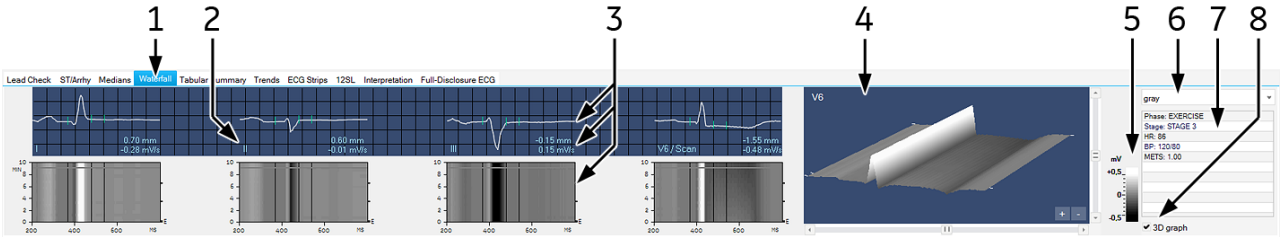
4 Median label (the complex is updated at the time interval selected in the *Protocol Editor*).

5 Display other median complexes backwards or forwards.

Waterfall

This window displays a graphic color representation of the median beat changes in the course of the test (updated at 30 second intervals).

Click anywhere in the waterfall to display the median complex and measurement of the corresponding point in time (associated phase, stage, HR, BP, and METS appear at the right).



1 Click the tab to display the *Waterfall* window.

2 Click the lead label to change the displayed leads.

3 Median complex, ST measurement and corresponding waterfall.

4 Three-dimensional graph.

5 Color code of the different amplitudes in mV.

6 Click to select the color menu.

7 View or hide 3D graph.

Tabular Summary

The *Tabular Summary* window displays test data in two tabular formats:

- stage format: 1 line per stage, or
- detailed format: 1 line minimum per 30 seconds

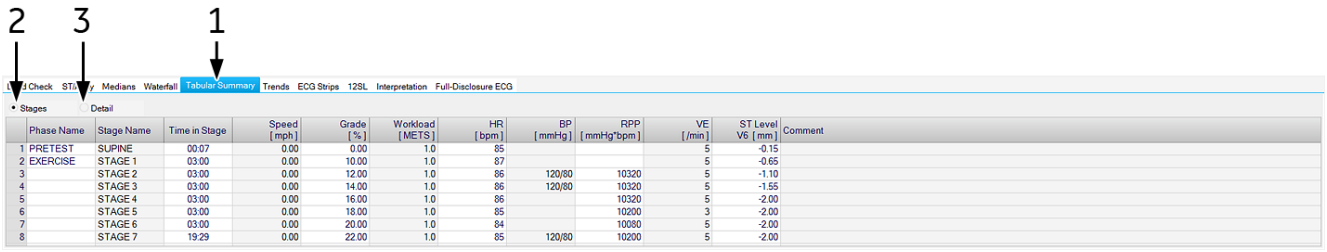
See "Configuring the Tabular Summary" on page 12-9.

Use the detailed format to enter or edit data.

1. Click the value to change.
2. Enter the new value. Edited values are bold.

To enter new data:

1. Click in an empty field.
2. Enter the new value.



	Phase Name	Stage Name	Time in Stage	Speed [mph]	Grade [%]	Workload [METS]	HR [bpm]	BP [mmHg]	RPP [mmHg*bpm]	VE [/min]	ST Level V6 [mm]	Comment
1	PRETEST	SUPINE	00:07	0.00	0.00	1.0	85			5	-0.15	
2	EXERCISE	STAGE 1	03:00	0.00	10.00	1.0	87			5	-0.65	
3		STAGE 2	03:00	0.00	12.00	1.0	86	120/80	10320	5	-1.10	
4		STAGE 3	03:00	0.00	14.00	1.0	86	120/80	10320	5	-1.55	
5		STAGE 4	03:00	0.00	16.00	1.0	86		10320	5	-2.00	
6		STAGE 5	03:00	0.00	18.00	1.0	85		10200	3	-2.00	
7		STAGE 6	03:00	0.00	20.00	1.0	84		10080	5	-2.00	
8		STAGE 7	19:29	0.00	22.00	1.0	85	120/80	10200	5	-2.00	

1 T*abular Summary* tab.

2 Display the stage format: 1 line per stage.

3 Display the detailed format: 1 line per 30 seconds.

METS Formula (Metabolic Equivalents)

Treadmill

$$METS = \frac{(speed \times 26.8 \times 0.1) + (grade/100 \times 1.8 \times speed \times 26.8) + 3.5}{3.5}$$

speed = miles per hour

grade = percent

$$METS = \frac{(speed \times 0.1) + (grade/100 \times 1.8 \times speed) + 3.5}{3.5}$$

speed = meters per minute

grade = percent

Bicycle Ergometer

$$METS = \frac{12.3 \times load + 3.5 \times weight}{weight \times 3.5}$$

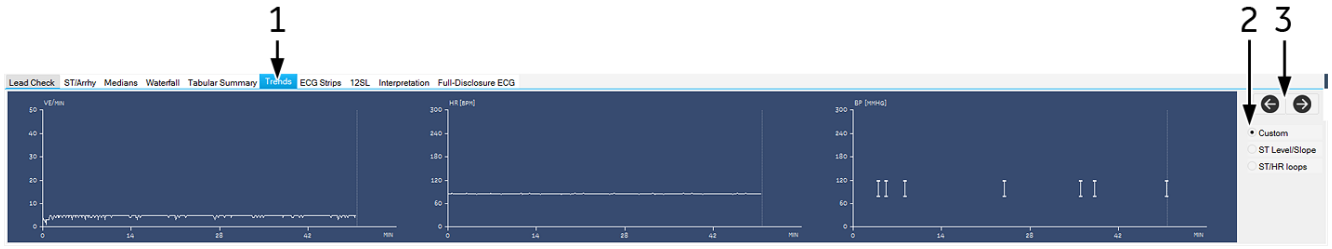
load = Watt

weight = kg

Between two stages, the METS value will be interpolated. The correct METS value of a stage is reached after a stage time of 60 seconds (default value, can be changed, see section "Miscellaneous 1 Tab" on page 12-15).

Trends

The *Trends* window displays graphic trends of different parameters. The trends are updated in 30 second intervals.



1 *Trends* window tab.

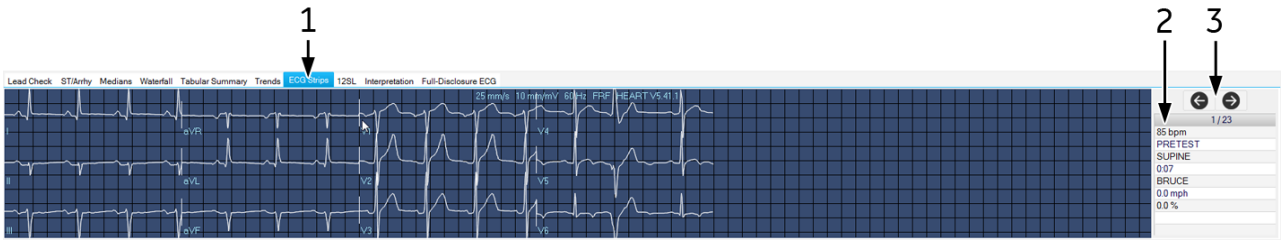
2 Display other trend formats.
Custom to display user configured trends.
ST Level/Slope to display the trend of ST level and slope versus time.
ST/HR Loops to display the two-dimensional representation of ST level versus HR (see section "Configuring Trends" on page 12-10).

3 Click to display other trend displays backwards or forwards.

ECG Strips

The *ECG Strips* window displays 10-second ECG strips:

- Stored during the last 10 seconds of each stage.
- Acquired manually.
- Acquired automatically as configured (see section "Protocol Editor Tab" on page 12-12).



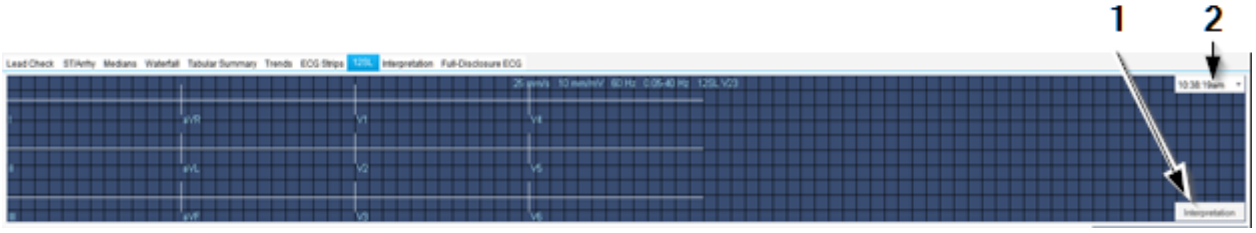
1 Open the *ECG Strips* window.

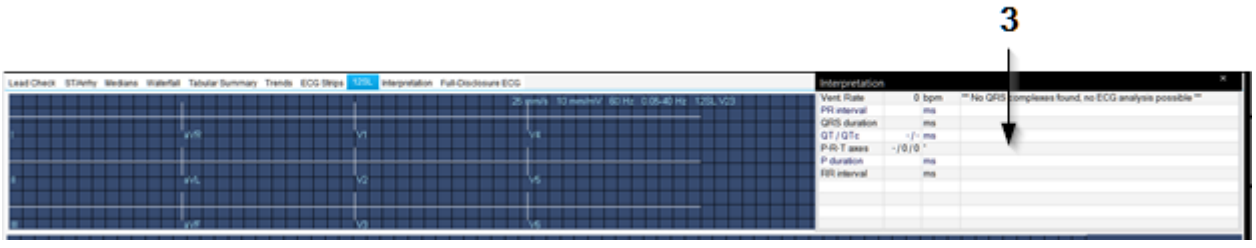
2 Test data of the ECG strip.

3 Display the other ECG strips.

12SL

The *12SL* window displays the 12SL resting ECG measurements and interpretation acquired by pressing **12SL** during preacquisition**,** pretest and recovery.





1 Display the interpretation.

2 Select the recording.

3 12SL measurements and interpretation.

Note

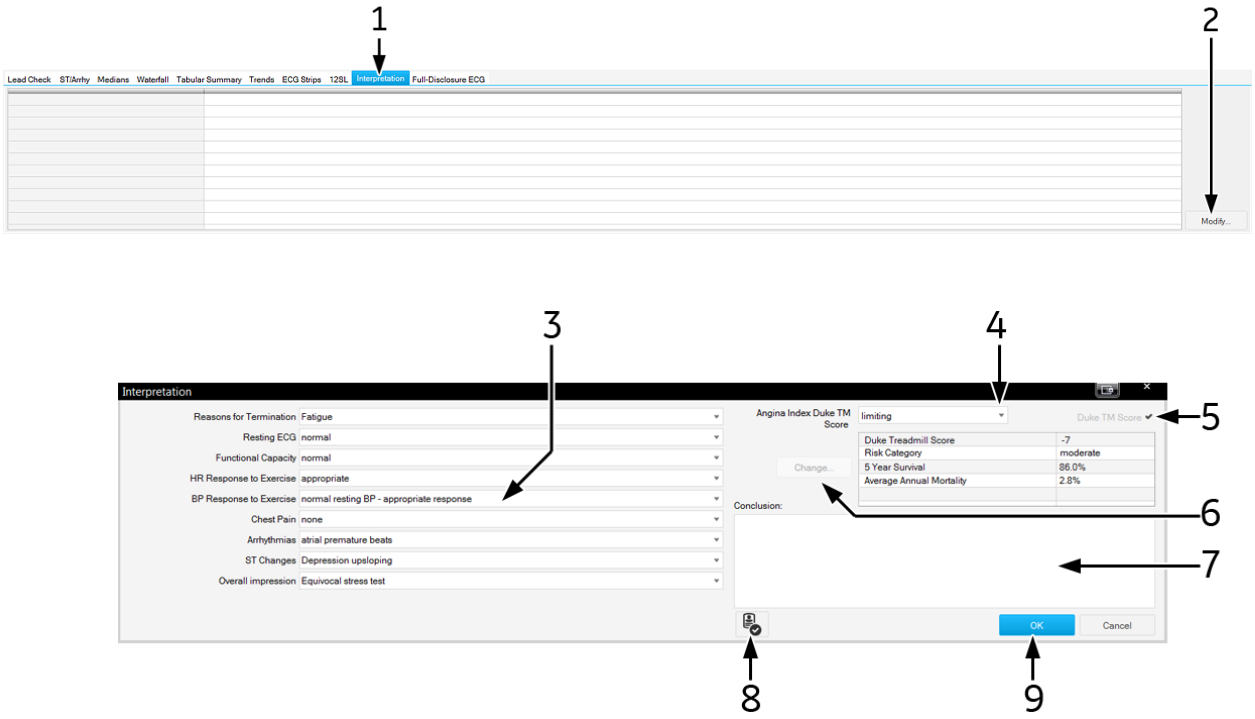
The vector loop is saved with the 12SL report only if the message *Median update ceased... Relearn* has disappeared from the *ST/Arrhy*

window at the time the 12SL report is stored.

The system stores up to five 12SL reports.

Interpretation

The physician can enter test interpretation information in the *Interpretation* window.



1 *Interpretation* tab.

2 Enter or edit the interpretation.

3 Enter or select summary statements for the different interpretation categories and for the Overall Impression.

4 Set the Angina Index Duke TM Score.

5 Include the Duke Treadmill Score in the Test Results and in the Final Report..

6 Click to edit the Duke Treadmill Score.

7 Enter the Conclusion.

8 Confirm the test results.

9 Clear the window.

Full-Disclosure ECG

By selecting the Full disclosure, you can view the full disclosure ECG. While conducting the test, you can enable the refresh option to view the latest values.

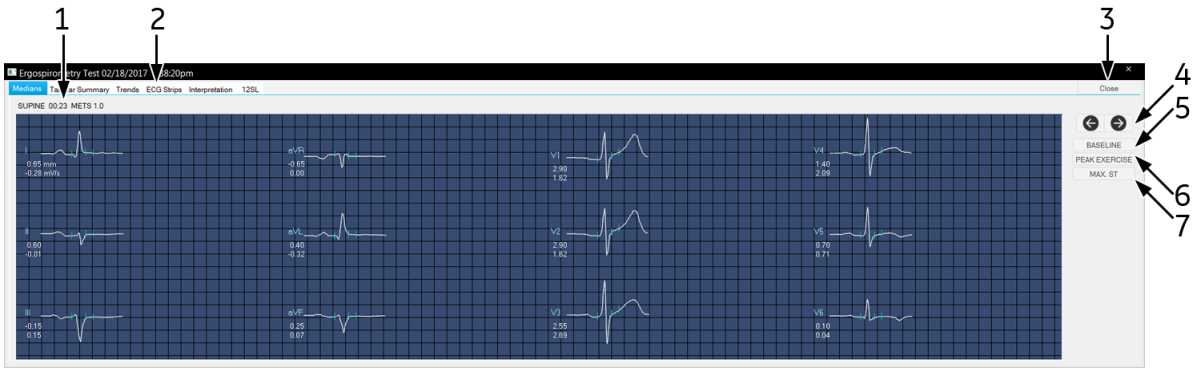
The operating controls in the full disclosure window are explained in section “Full Disclosure ECG” on page 6-30.

Comparing Previous Test Data

At any point in the test, you can compare the current data with that of a previous test:

1. Click *Previous Tests Current Patient*.
2. Double-click the test to review:

Page 1 of the median complexes will appear in the lower part of the screen for reference.



1	Details of the displayed median complexes.
2	Tabs to view other ECG data windows.
3	Clear the second test window.
4	View more median complexes.
5	Display the baseline medians.
6	Display the peak exercise medians.
7	Display the medians with the most significant ST depression.

Recovery Phase

Press the **recovery** button to advance to the recovery phase.

The clock begins timing the recovery phase. In recovery, the treadmill speed and grade or the bicycle load will change according to the protocol configuration.

Test End Phase

1. Press the **test end** button to end the test and start the test end phase.
2. Click *Yes* to confirm the test end. The Interpretation window appears with the patient's ECG waveforms.
3. Press the test end button to stop the clock and stop the ECG measurement data.

Ending the Phase

1. Enter or select the *Reasons for Termination* (multiple selections are permitted).
2. Select the *Angina Index* which is necessary to calculate the Duke Treadmill Score.
3. Enter or select summary statements (multiple selections are permitted).
4. Enter the *Conclusion*.
5. Click *Modify* to edit the Duke Treadmill Score. Enable the Duke TM Score to include it in the Test Results and in the Final Report.
6. Confirm the test results.
7. Click *OK* to clear the window. The Interpretation window and the test end menu tabs appear.

Note

Real-time reports can be printed with the following buttons on the function keypad:

12 lead

medians

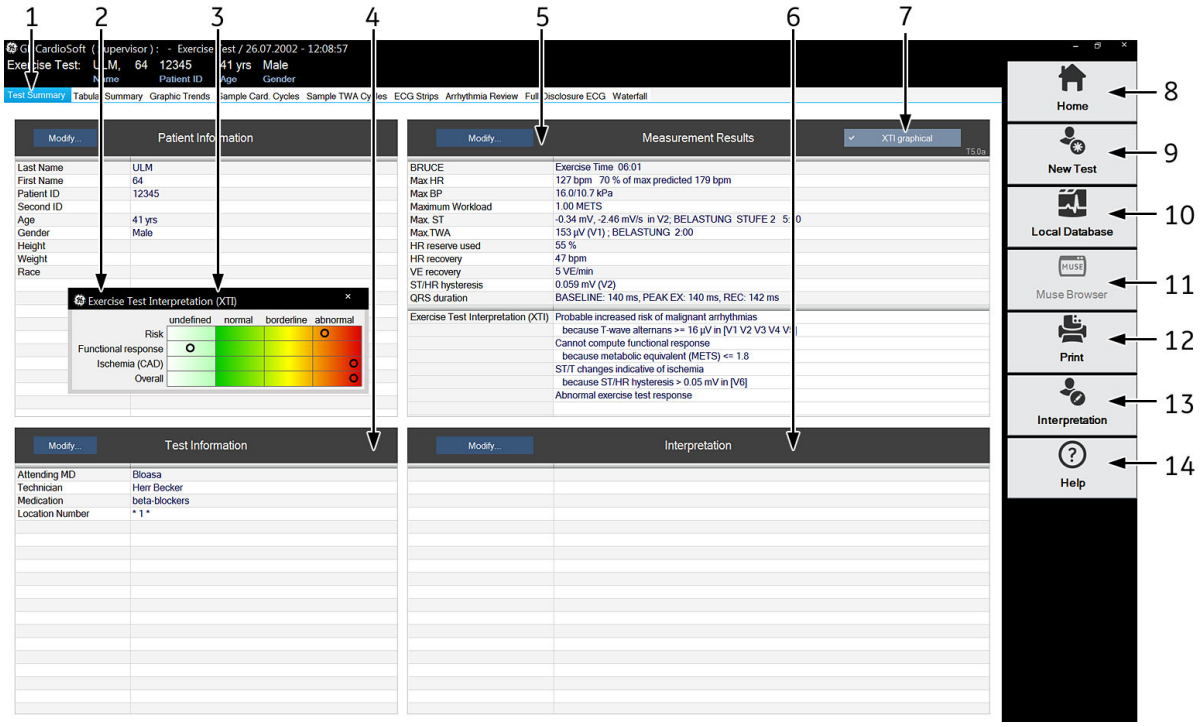
rhythm

recall (data is not saved).

8. Click the test end menu tabs to review and edit the data.
9. Click *Print* or press **test end** to print the final report.
10. Click *Review* to review the stored test information. This will end the display of the patient ECG waveforms, or click *New Test* to start a new test.

After the Test — Post Test Review

Test Summary



1 *Test Summary* tab.
2 Patient Information.
3 Exercise Test Interpretation (XTI)
4 Test Information.
5 Measurement Results.
6 Physician's interpretation.
7 Select to display XTI window.
8 Return to home screen.
9 Display patient list for a new test.
10 Display a list with tests of the current patient in the local database.
11 VIew patient's tests from MUSE database.
12 Open the print setup window.
13 Open the interpretation window.
14 Open Help.

The *Modify...* buttons lets you to edit or complete the data in the respective areas.

- *Patient Information*: The *Patient Information* window opens.
- *Test Information*: The *Test Information* window opens.
- *Measurement Results*: A window opens where you can edit the measurement results. Edited measurement results are identified with an asterisk (*). You can choose whether or not to display the system evaluation.

Note

After opening the edit window with *Modify...*, you can select a check box to remove the *Exercise Test Interpretation* from the *Measurement Results* window.

- *Interpretation*: A window opens where you can generate the test interpretation ("Test End Phase" on page 6-19).

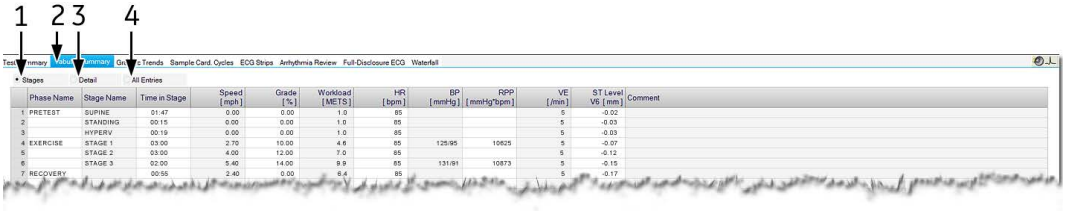
For details on the Graphical XTI output, see the *Physician's Guide to GE Stress Systems*, part no 2051167-002.

Tabular Summary

The *Tabular Summary* window displays test data in three tabular formats:

- Stage format: 1 line per stage.
- Detailed format: 1 line minimum per 30 seconds.

All entries.



1 Display the stage format (1 line per stage).

2 *Tabular Summary* tab.

3 Detailed format (1 line minimum per 30 seconds).

4 Display all entries.

Use *Detail* or *All entries* to enter or edit data.

1. Click the value to change.
2. Enter the new value. Edited values are bold.

To enter new data:

1. Click in an empty field.
2. Enter the new value.

Note

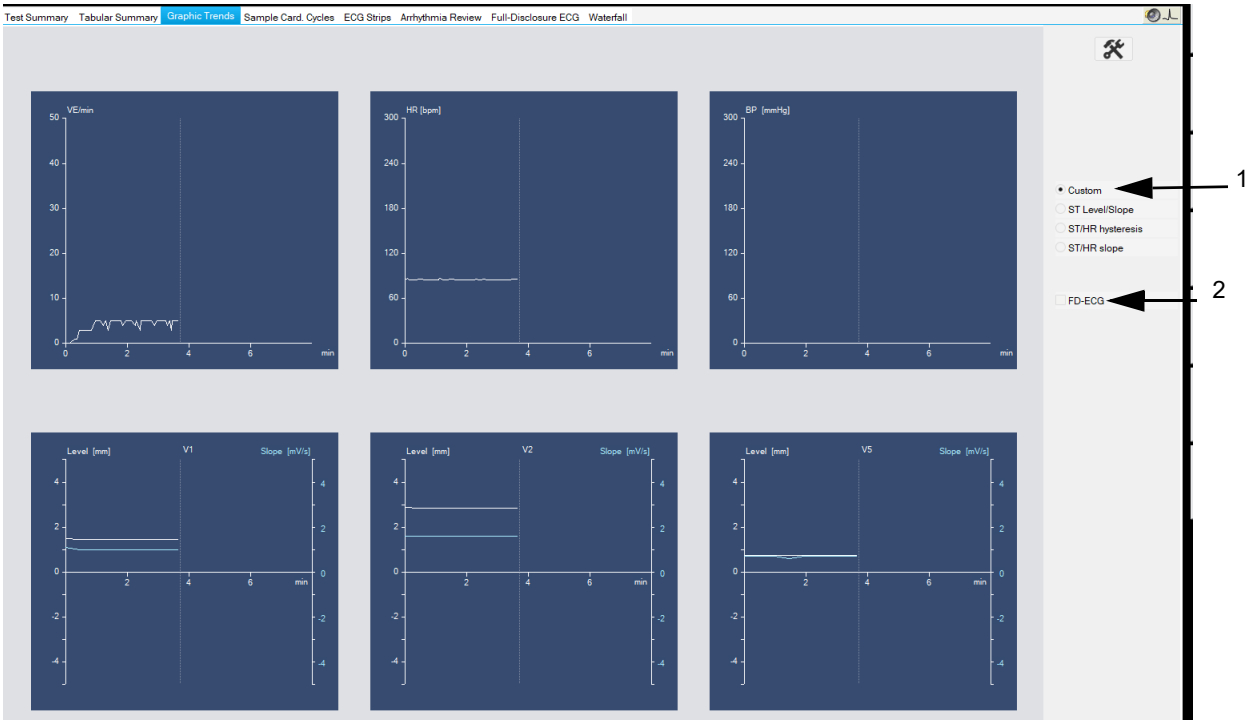
Only the stage format of the *Tabular Summary* is transferred to the MUSE system.

METS Formula

See "METS Formula (Metabolic Equivalents)" on page 6-15 for details of the METS formulas.

Between two stages, the METS value will be interpolated. The correct METS value of a stage is reached after a stage time of 60 seconds (default value, can be changed, see section "Miscellaneous 1 Tab" on page 12-15).

Graphic Trends



1 Display other trend formats.
- *Custom* to display user configured trends.
- *ST Level/Slope* to display the trend of ST level and slope versus time.
- *ST/HR Loops* to display the 2-dimensional representation of ST level versus HR. To expand the ST and HR axes, click *Auto Scale ST* and *Auto Scale HR* (see section "Configuring Trends" on page 12-10).

If you purchased the STHY option (ST/HT Hysteresis), *ST/HR Hysteresis* will be displayed here instead of *ST/HR Loop*.
- *ST/HR Slope* to display the heart rate-adjusted slope for all leads.
- *TWA* to display the TWA trends.

2 Display the full disclosure ECG.

Note

The system starts collecting trend data at the beginning of the exercise phase.

Viewing Medians, Replacing max. ST Changes

1. Locate the ST value in the trend graph of interest and click: a new window with the corresponding median complex will open.
2. Click on the ST value in the median complex window: a new window with the new and old ST values appears.
3. Click *Yes* and the ST value will be changed.

Viewing TWA Medians, Replacing max. TWA Values

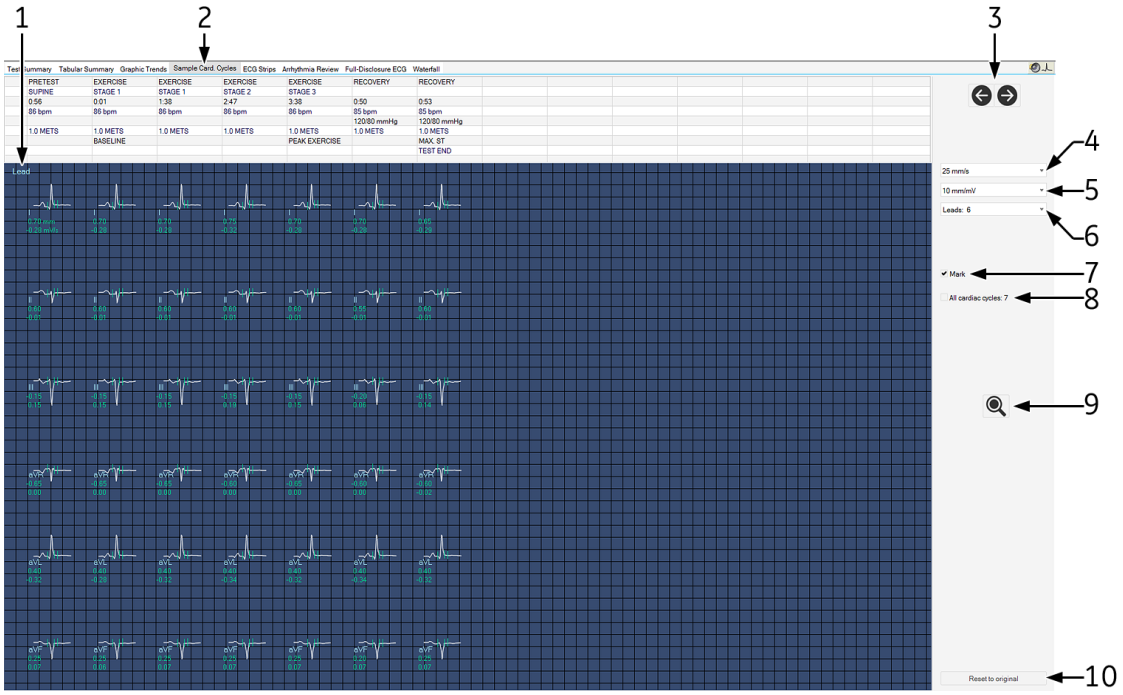
1. Locate the TWA value in the trend graph of interest and click.
2. A new window with the corresponding median complexes will open.
3. Click on the TWA value in the median complex window: a new window with the new and old TWA values appears.
4. Click *Yes* and the TWA value will be changed.

Note

Dashed lines appear in case of noisy signal and/or when the heart rate is too high (see *TWA Heart Rate Limit* in Chapter 12, "System Settings" under "TWA Tab" on page 12-18).

Sample Cardiac Cycles

This screen shows the median complexes collected at each stage, beginning with the pretest phase.



Note

Reanalyze the sample cardiac cycles as described under "Reanalysis" on page 6-25.

1 Click the lead label to change the displayed leads.

2 Display the *Sample Cardiac Cycles*.

3 View more sample cardiac cycles.

4 Show and hide the measurement marks.

5 Select the speed of the displayed medians.

6 Select the gain for the displayed medians.

7 Select the number of lines (1, 3, 6).

8 Number of medians shown per stage:
All cardiac cycles (at intervals of 30 seconds) or only one cardiac cycle

9 Activate the zoom and reanalysis.

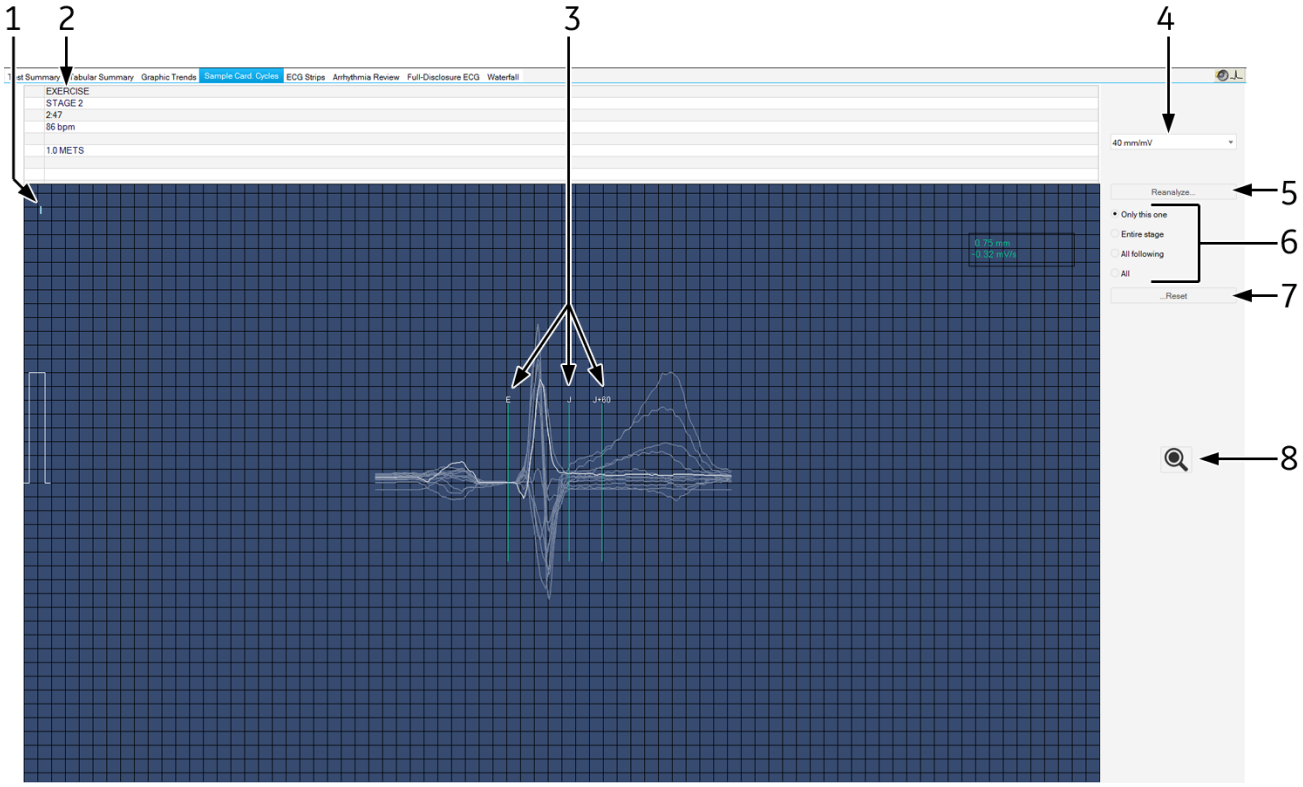
10 Click *Reset to original* to discard the results of the reanalysis and return to the original measurements.

Reanalysis

Reanalysis allows you to manually change the position of the ST measurement marks. On the reanalysis screen the medians of all leads are superimposed. The currently selected lead is highlighted. The measurement marks determined by the system are indicated. The marks above the baseline can be edited.

To activate reanalysis

- Click the Zoom icon on the *Sample Cardiac Cycles* screen
- position it over a complex and click the left mouse button



1 Select another lead.
2 Details of the selected median complex.
3 Measurement marks determined by the system.
5 *Reanalyze*.
6 Select the complexes to reanalyze.
7 Reset the measurement marks to their original positions.
4 Change the gain.
8 End reanalysis and return to the *Sample Cardiac Cycles* window.

Performing Reanalysis

1. Click a measurement mark above the baseline and hold the mouse button depressed.
2. Move the mark to its new position and release the mouse button.
3. Adjust the other marks in the same way.
4. Select the complexes to reanalyze.
5. Click *Reanalyze*.
6. Click *Reset* and *Reanalyze* to restore the original analysis results. (*Reset to original* restores the original results for all complexes of the entire exercise test).

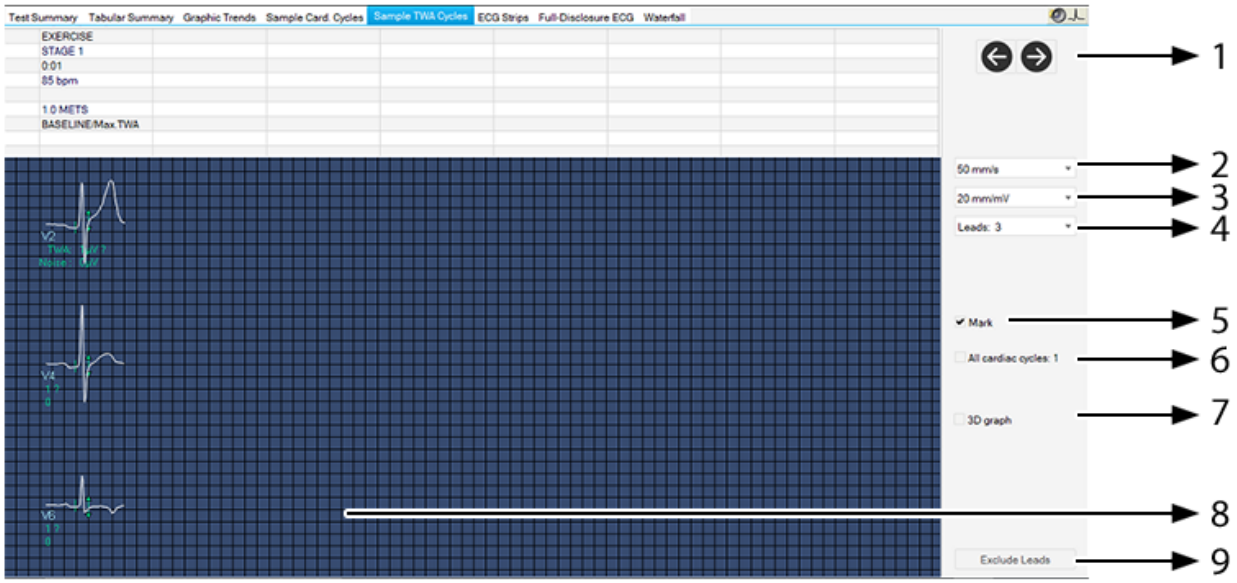
Performing Measurements on the Median Complex

Amplitudes (mV), intervals (ms) and slopes (mV/s) can be measured on all sample cardiac cycles:

1. Position the cursor on the first measurement point and click. A caliper appears.
2. Position the cursor on the second measurement point and click. Now you will see
   - the second caliper
   - the measuring line
   - the measurement results
3. Click the right mouse button to remove the measurement points.

Sample TWA Cycles

This screen shows the Sample TWA Cycles. Questionable values are identified with a question mark?. Two-headed arrows identify the position where the TWA value was determined. Individual leads can be excluded. You may then repeat the analysis without these leads. This method prevents false-positive TWA values, particularly when permanently disturbed leads are excluded.



1 Click to view more sample TWA cycles.

2 Select the speed of the displayed medians.

3 Select the gain for the displayed medians.

4 Select the number of leads (1, 3, 6).

5 Click to show and hide the measurement marks.

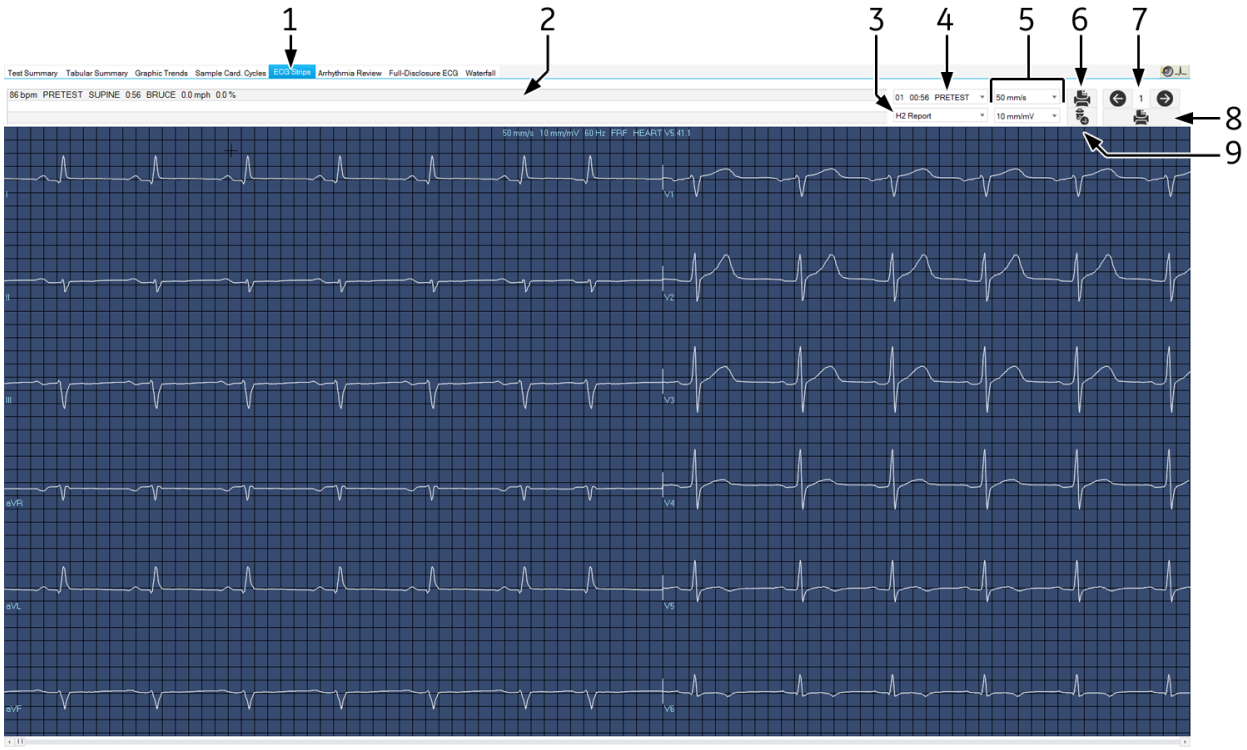
6 Number of medians shown per stage:
- All cardiac cycles (at intervals of 30 seconds)
- Only one cardiac cycle

7 Select the 3D graph to display a three-dimensional representation of the medians.

8 Position where the TWA value was determined.

ECG Strips

This screen displays 10-second ECG strips
- stored during the last 10 seconds of each stage
- acquired manually, or
- acquired automatically as configured in the *Protocol Editor*.



1 *ECG Strips* tab.

2 Details of the selected ECG strip.

3 Select the report.

4 Display the other ECG strips

5 Change the speed and gain.

6 Print the displayed ECG strip.

7 Display the other ECG strips.

8 Click icon to include the ECG strip in the test report (check mark) or to exclude it from the test report (printer crossed out).

9 Delete the displayed ECG strip.

Note

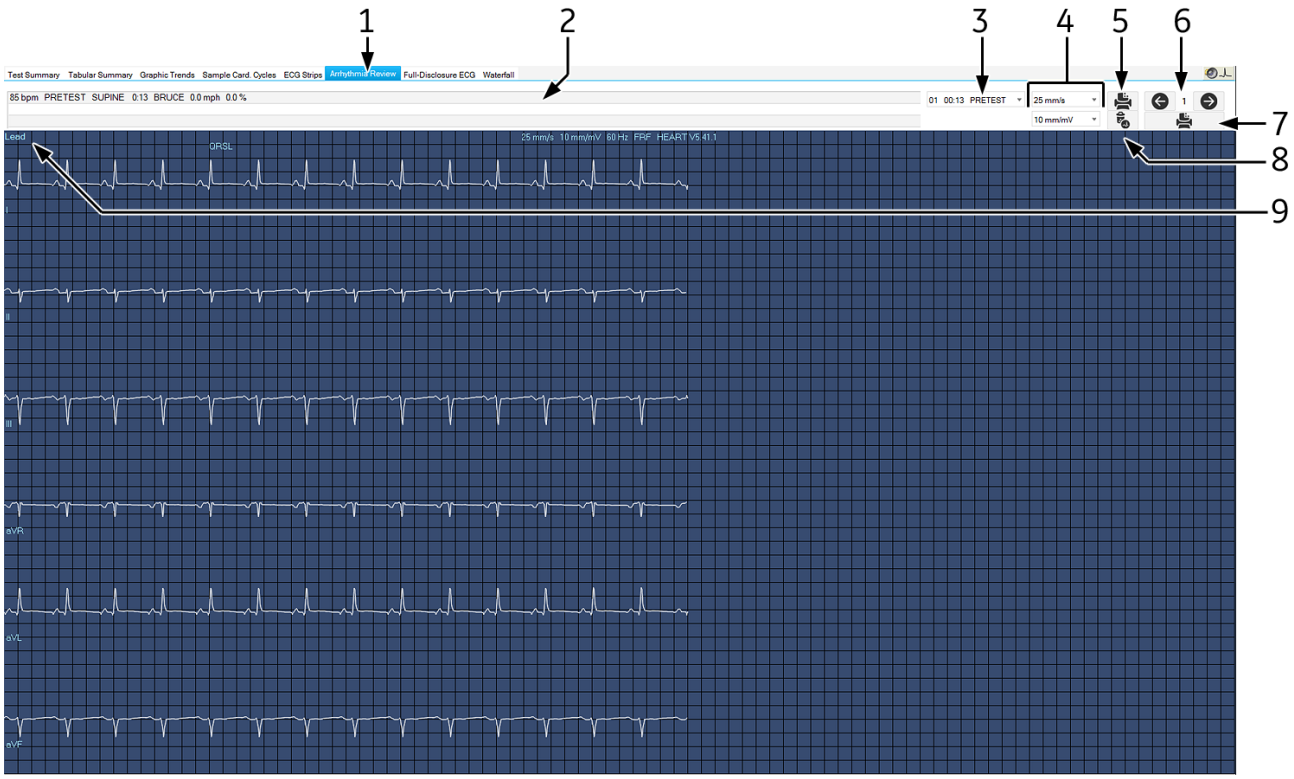
You can perform measurements as described under "Performing Measurements on the Median Complex" on page 6-26.

Note

Median H1/H2 report are not displayed on screen and are for printing purpose only.

Arrhythmia Review

The system will save a 10-second ECG strip each time an arrhythmia occurs and when the *Event Marker Full Disclosure* button is clicked on the acquisition screen (to a maximum of 20). When the event memory is full, the strips will be overwritten according to preset priorities.



1 *Arrhythmia Review* tab.
2 Details fo the displayed strips.
3 Select the report.
4 Change the speed and gain.
5 Print the displayed ECG strip.
6 Display the other ECG strips.
7 Click icon to include the ECG strip in the test report.
8 Delete the displayed ECG strip.
9 View other *Arrhythmia Review* leads.

Note

You can perform measurements as described under "Performing Measurements on the Median Complex" on page 6-26.

Significant arrhythmias are displayed red.

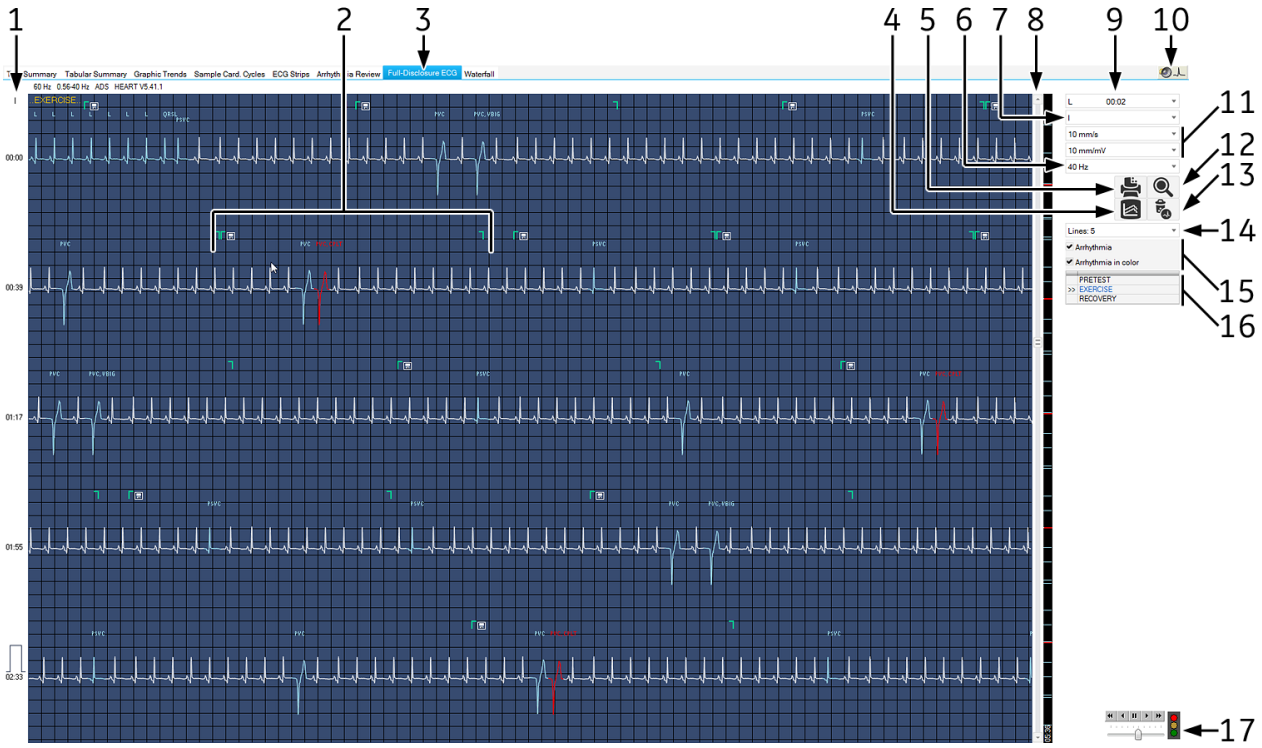
Arrhythmias (descending priority)	
- patient's learned typical QRS complex	QRSL
- asystole[1], limit value 3 s	ASYSTO
- ventricular fibrillation/flutter[1]	VFIB
- ventricular tachycardia [1]	VTAC
- ventricular run (minimum of 3 consecutive PVCs)[1]	RUN

Arrhythmias (descending priority)	
- ventricular couplet (2 consecutive PVCs)[1]	CPLT
- atrial fibrillation	AFIB
- pause of 2 missed beats[2]	PAU2
- pause of 1 missed beat[2]	PAU1
- ventricular bigeminy	VBIG
- paroxysmal supraventricular tachycardia	PSVT
- pacer error	PERR
- ventricular escape beat	ESC
- premature ventricular contraction	PVC
- premature supraventricular contraction[2]	PSVC
- pacemaker capture	PCAP
- absolute pause	PAUA
- artifact[3]	A
- learn phase[3]	L

1. significant arrhythmias
2. The arrhythmia analysis algorithm will not output these events in the presence of supraventricular arrhythmia (e.g. atrial fibrillation).
3. not in arrhythmia window, no arrhythmia strip (only full disclosure ECG)

Full Disclosure ECG

The system will save the full disclosure ECG only if configured (see section "Miscellaneous Tab" on page 12-22). On this screen you see one lead of the full disclosure ECG. The events identified by the rhythm analysis algorithm may be color-coded. On the display you can also see ADS.



1 Change displayed lead.

2 Marks beginning and end of an arrhythmia.

3 Open the *Full Disclosure ECG* window.

4 Go to the trend display.

5 Print the full disclosure ECG or selected segments.

6 Frequency.

7 Open a list with all leads.

8 Scroll box to display different time windows. The markers to the right of the scroll bar allow direct access to the corresponding events.

9 Show all identified arrhythmias.

10 Play the audio ECG.

11 Gain and speed.

12 Activate the zoom function.

13 Delete the full disclosure ECG.

14 Select the number of waveforms viewed.

15 Show and hide the arrhythmia strip markers.

15 Arrhythmia color coding.

16 Phase.

17 ECG waveform scrolling, adjust the scroll speed with the slider.

Printing the Full Disclosure ECG

You can either print the entire full disclosure ECG or a selected segment.

Selecting an ECG Segment

1. Click to mark the beginning of the segment. A flag appears.
2. Click again to mark the end of the segment. A second flag appears.

Printing

1. Click the printer icon. The print setup window opens.
2. Select the paper speed.
3. Click Format-1 option to print only one lead.
4. Select the lead.
5. Click Format-2 option to print multiple leads, and select the leads.
7. Click *Save* to save the print setup.
8. Start the printout or close the window with *Cancel*.

Note

Time printed on the report is phase time and it may differ from what is displayed on the screen.

Enabling the Zoom Mode

1. Click the zoom icon.
2. Position the magnifying glass on the region of interest and click.

An enlarged view of the selected region appears.

The operating controls remain the same. When you click the printer icon, however, only that page will be printed.

Audio ECG

The audio ECG allows the medical staff to assess the exercise test quickly and easily.

The ECG is played back at 60 times the original speed, so that you can listen to a 10-minute recording in 10 seconds.

Playback of the recording is in stereo: lead V2 is assigned to the left channel, lead V5 to the right channel.

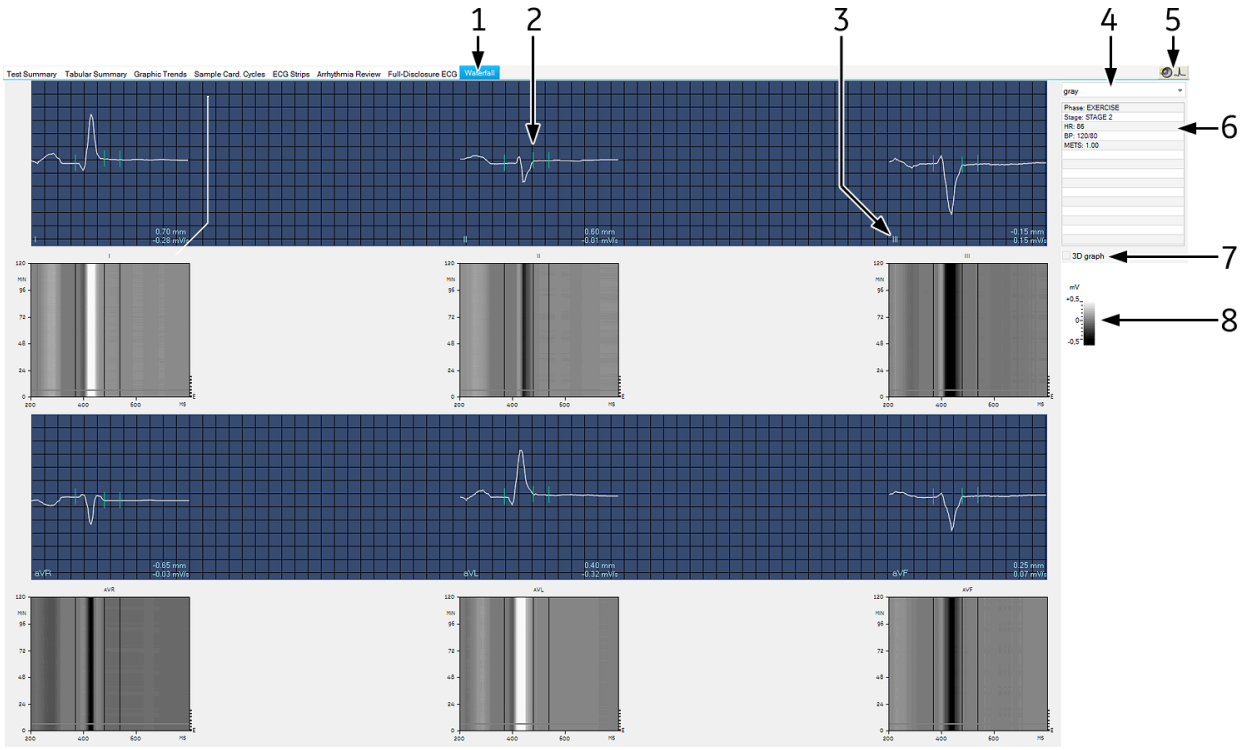
The continuously increasing heart rate corresponds to the exercise phase, the subsequent decrease, to the recovery phase. Arrhythmias can be heard very clearly.

Also see Audio ECG Physician's Guide, Part No. 2051167-002.

Waterfall

The *Waterfall* display is a graphic color representation of the median beat changes in the course of the test (updated at 30 second intervals).

Click anywhere in the waterfall to display the median complex and measurement of the corresponding point in time (associated phase, stage, HR, BP, and METS appear at the right).



1 *Waterfall* tab.

2 Median complex selected in the waterfall.

3 Click the lead label to change the displayed leads.

4 Color code of the different amplitudes in mV.

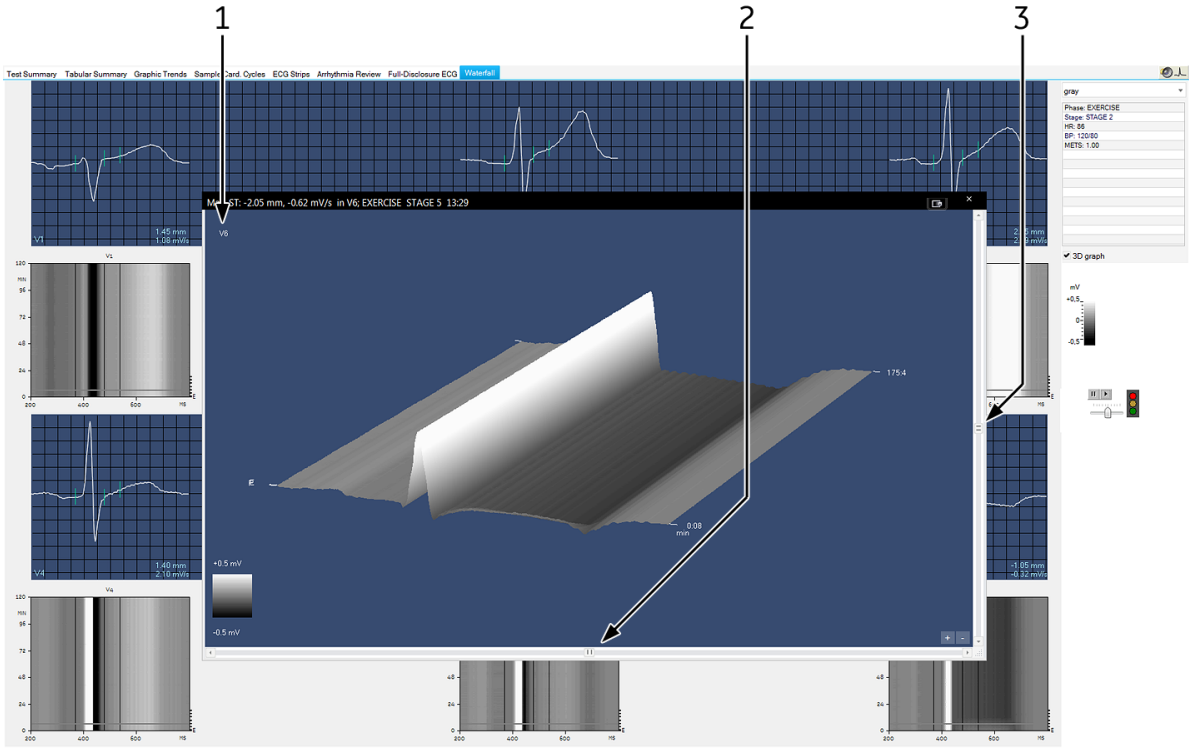
5 Click to play the audio ECG.

6 Details of the selected median complex.

7 Select check box to view the 3D graph.

8 Select the color menu.

3D Graph



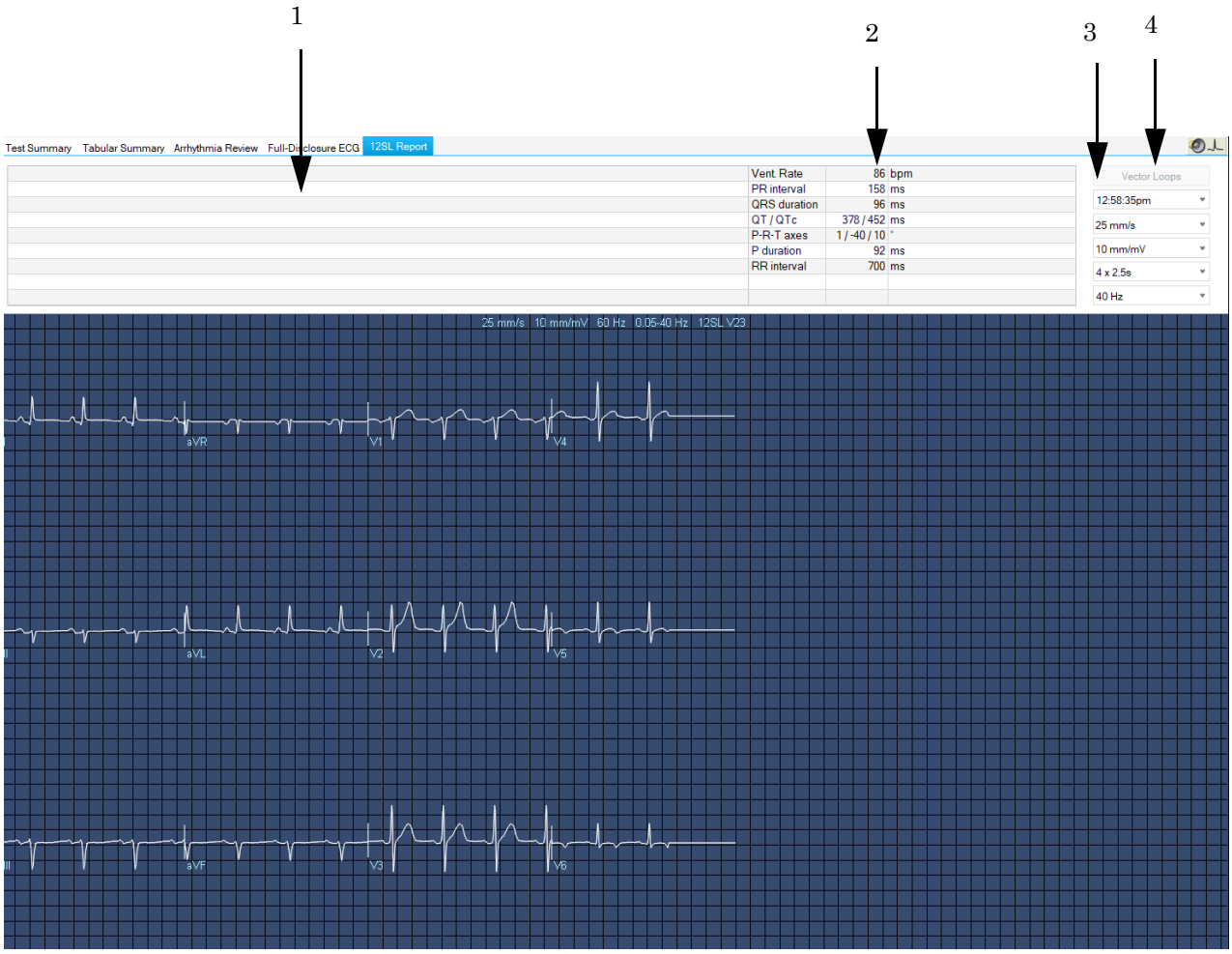
1 Click to select another lead.

2 Click to rotate the display horizontally.

3 Click to rotate the display vertically.

12SL Report

This screen shows the measurements from the 12SL ECG analysis.



1 Analysis results.

2 Vent Rate, PR interval, QRS duratin, QT/QTc, P-R-T axes, P duration, RR interval.

3 Change the speed and gain.

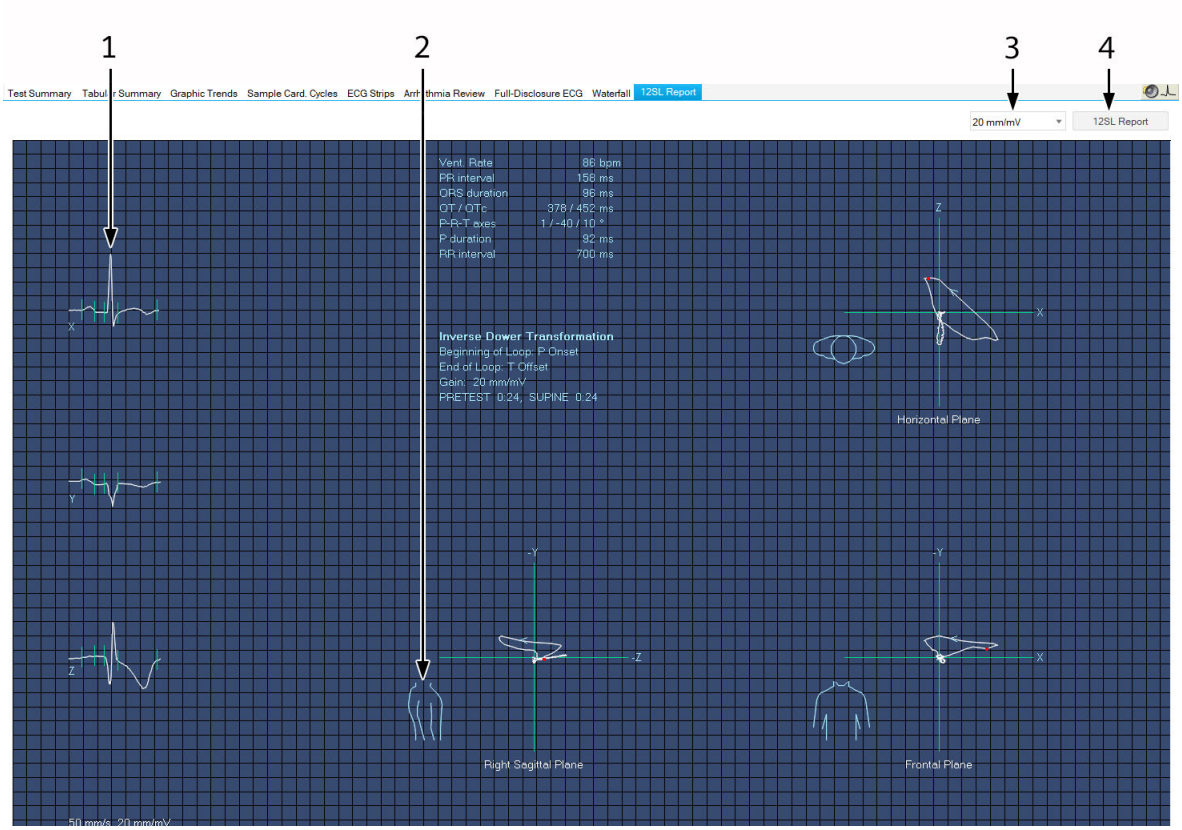
4 View the corresponding Vector Loops (see next page).

Note

Median H1/H2 report are not displayed on screen and only for printing purpose.

Vector Loops

This screen shows the median complexes of the orthogonal FRANK leads X, Y and Z as well as the vector loops in three planes.



1 Median complex.

2 Click torso to toggle between right and left sagittal planes.

3 Change the gain.

4 Return to the *12SL Report* window.

Note

You can perform measurements as described in section "Measuring the ECG" on page 5-12.

The vector loop is saved with the 12SL report only if the message *Median update ceased... Relearn* has disappeared from the *ST/Arrhy* window at the time the 12SL report is stored.

Report Printout

Click the *Print* button to print the report. The print setup window opens where you can temporarily adjust the settings for the printout. Refer to section "Run the Final Report" on page 12-14 for details on changing the setup permanently.

1. Select the documents for the report (*Configured Report*, *Tabular Summary*, *Graded Exercise Summary Report* etc.): In the *Trend Reports* section, select the report formats to print.
2. Select the gain.
3. Select the *Configured Report* format).
4. Select the number of copies for each report section.
5. Select the printer.
6. Check the total number of pages.
7. Initiate the printout.
8. Click *Deselect/Select* to cancel the selections.

Note

Select the *ECG Grid* option if you print on plain paper.

Temporary changes to the selections will be lost when you close the window.

Report Formats

In-Test Reports

Format	Description
12SL	Interpretative resting ECG with analytical statements on morphology, rhythm, and conduction. Measurements of rate, intervals and axes. Available before the test, in pretest and recovery. Formats include: 4 x 2.5; 4 x 2.5 +1, 2 x 5; H2 (5 s ECG at a speed of 50 mm/s x 6) and H1 (6-lead ECG at 12.5 mm/s, Medians at 50 mm/s).
3, 6, 12 or 15-Lead Report	Presents raw ECG data in various formats: 4 x 2.5 s ECG; 4 x 2.5 +1 (2.5 seconds of raw data plus 1 continuous 10 second recording of continuous rhythm); 2 x 5 (5 seconds of raw data); 1 x 10 (10 seconds of raw data); H2 format (5 seconds of raw data at a speed of 50 mm/s x 6).
Rhythm Report	A continuous, real-time recording of raw ECG data: 3, 6, 12 leads. Leads for arrhythmia report correspond to leads on the screen (not with laser printer).
Arrhythmia Report	Automatic 10-second documentation of arrhythmias showing 2.5 seconds of raw data prior to ectopic beat. Leads for arrhythmia report correspond to leads on the screen.
Recall Report	A delayed recording of raw data 10 seconds in duration: 3, 6, 12 leads.
Comparative Medians Report	Baseline and current medians followed by 2.5 seconds of real-time rhythm in 12 leads. ST level and ST slope reported for each lead. Also comes in H1 Medians format of 12 medians at 50 mm/s + 6 leads (selectable) of 10 seconds of rhythm at 12.5 mm/s.
Linked Medians Report	4 x 2.5 with rhythm lead. 3 channels of median beat which are linked together at the current heart rate with a fourth 10-second channel of raw, real-time rhythm.

The formats may differ slightly when the *Swedish Reports* are selected.

Final Reports

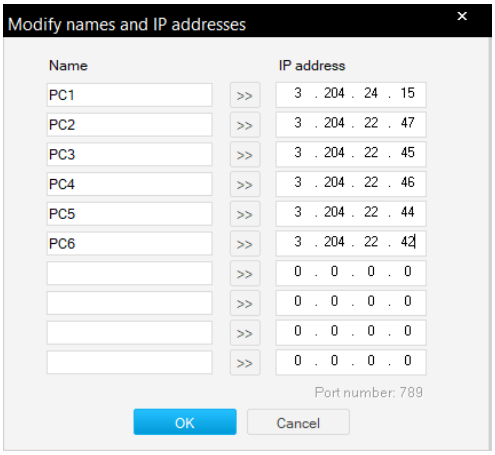
Format	Description
Configured Report	User-configured portrait-style final report. User formats narrative text and selects data fields to create report template. Configured Report automatically merges text and data according to templates selected. For details on the Configured Report, see "Report Editor" on page 12-6.
Tabular Summary	Tabular Summary of test by stage including time, speed, grade, workload, MET level, heart rate, blood pressure, comments, with optional selections for double product (RPP), ST level, SpO_2 and user-configured entries. Can also be printed as Detailed Summary in minimum of 30 second intervals. For instructions on Tabular Summary configuration, see section "Configuring the Tabular Summary" on page 12-9.
Graded Exercise Summary Report	One page overview of entire test with median morphologies for 12 leads from baseline and either max. ST depression or peak exercise. For max. ST depression, report only prints when a minimum of -0.5 mm of ST depression occurs in one of the following leads: I, II, III, aVF, V2 to V6 (V1, aVR, aVL excluded; for ST elevation, -aVR is excluded).
Selected Medians Report	Records median morphologies at baseline, max. ST depression, peak exercise and test end for 12 leads. For max. ST medians, column only prints when a minimum of -0.5 mm of ST depression occurs in one of the following leads: I, II, III, aVF, V2-V6. (V1, aVR, aVL excluded; for ST elevation, -aVR is excluded).
Sample Cardiac Cycles	Records median morphologies for 12 leads at user-defined intervals. Intervals defined in *Protocol Editor* for each protocol by configuration of Store Median interval; 25 or 50 mm/s.
Trend Reports	Records plots of PVCs, heart rate and blood pressure or any custom combination of parameters (Trends: Custom). Also produces trend report of ST level and slope versus time (Trends: ST Level/Slope, Trends: TWA). For details on the Trend Graphs, see "Configuring Trends" on page 12-10.
ST/HR Hysteresis	A two-dimensional representation of ST level versus heart rate in exercise and recovery phases.
ST/HR Slope	Records linear regression of heart rate-adjusted slope for all leads, plus median morphology of lead with highest slope.
ECG Strips	Report of all 12 leads (also medians and recall stored in 12-lead format) stored during the tests (manual or automatic). User can select all or some of the 12 leads to be printed.
Arrhythmia Review	Report of 20 stored arrhythmias showing 2.5 seconds of raw data prior to the ectopic beat through 2.5 seconds after the last. User can select all or some arrhythmias to be printed.
Vector Loops	Report showing Y, X, Z leads and three-plane vector loop display of horizontal, frontal and sagittal planes using Frank X, Y, Z lead set. Derived from associated 12SL report.
Sample TWA Cycles	TWA medians report (see "Sample TWA Cycles" on page 6-26).
Waterfall	Waterfall display report of all leads.
Swedish Median Report	Special medians format for Sweden. Only if *Swedish Reports* are enabled.
One Page Report	Generates one page overview of entire test which will be saved as PDF file.

Monitoring Remote Exercise Test Workstations

You can monitor an exercise test performed at remote stations from your PC. However, six stations can be viewed by other station at a time. The data in the vital signs window reflect the settings at the remote station. Conditions for the remote view function:

- The *Remote View* function is enabled at the remote station (see section "Miscellaneous 1 Tab" on page 12-15).
- The *pretest* phase has already started.

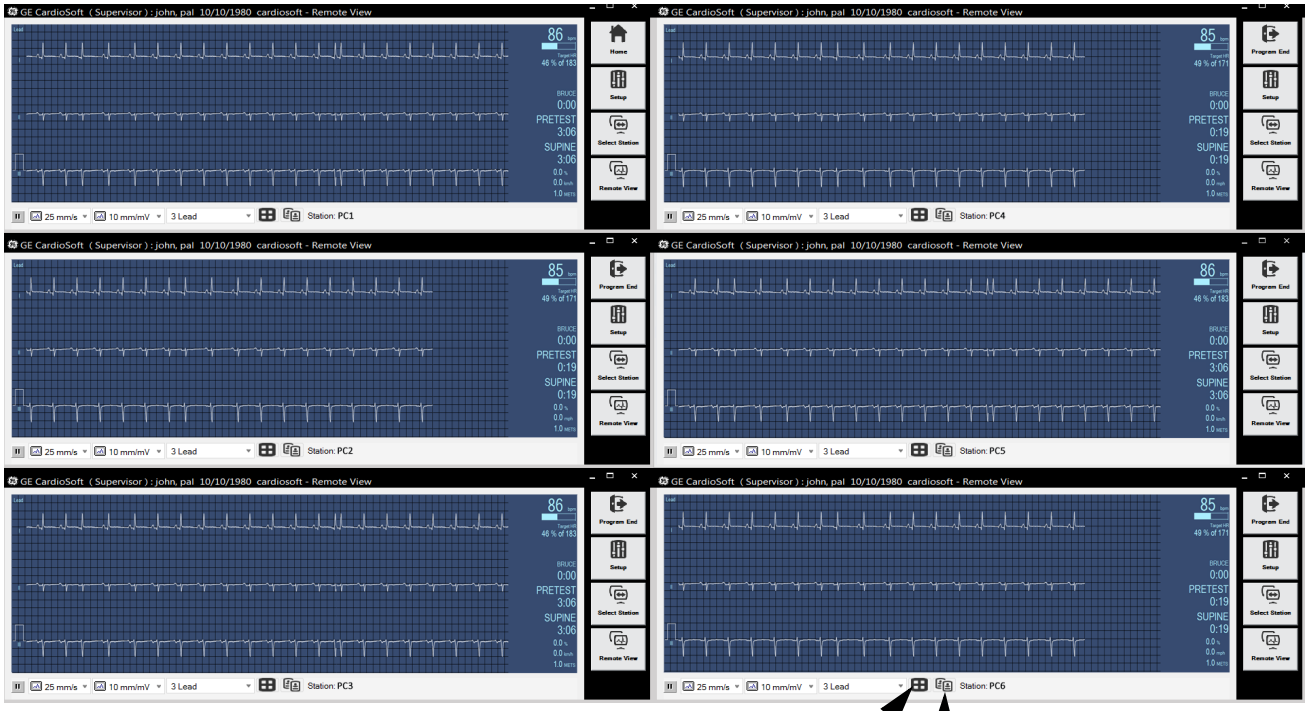
1. Click *Remote View* on the initial screen to view the remote exercise test screen.
2. Click *Setup* and enter the PC names in the left column of the window.
3. Click the arrow buttons to enter the corresponding IP address automatically. If the system does not find the IP address, you can enter the address manually.



4. Click *OK*.
5. Click *Select Station* and select the stations.
6. Click *Select*.

Note

Based on the available screen size and resolution, if more than one remote view window is opened, the display may not be good, it can be controlled by maximizing the screen size.


GE CardioSoft (Supervisor) : john, pal 10/10/1980 cardiosoft - Remote View
Station: PC1
Station: PC4
Station: PC2
Station: PC5
Station: PC3
Station: PC6
Rearrange Windows Side by Side
Rearrange Windows Cascading

7 Ambulatory Blood Pressure Measurement

For your notes

Ambulatory Blood Pressure Monitors

The following ambulatory blood pressure monitors can be connected to the system:

- TONOPORT V: blood pressure only, oscillometric method with RS232 Serial interface port and USB interface.
- TONOPORT VI: blood pressure, oscillometric, method with RS232 Serial interface port and USB interface.

Refer to the Tonoport Operator's Manual for example, and functionality information.

Caution

PATIENT HAZARD — Disconnect TONOPORT from the patient when it is connected to the PC.

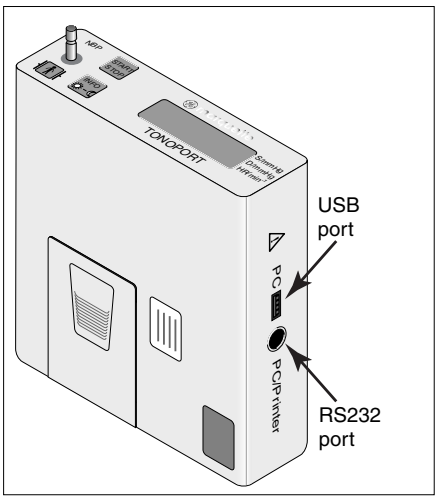
Note

Check that the correct port for the ambulatory blood pressure monitor is configured (see "Devices Tab" on page 12-42).

The blood pressure can be measured in kPa or mmHg. See "Country Settings Tab" on page 12-46.

TONOPORT V version 2.0 and later, and TONOPORT VI, can be connected to the serial port (RS232) or to the USB port. If the USB port is used, the required driver must be installed. Refer to the Software Installation chapter of the TONOPORT V and TONOPORT VI Operator's Manual for instructions.

Connecting the Ambulatory BP Monitor



TONOPORT V, version 2.0



TONOPORT VI

1. Turn the monitor off and on.
2. Wait for the time to be displayed, then connect the monitor to the PC.

Setting Up the Ambulatory Blood Pressure Monitor

Acquisition Screen



1 Measurement protocol details.

2 

Click to return to the initial screen.

3 

Click to connect the ambulatory blood pressure monitor to the system.

4 

Click to activate the programming mode. If a patient is selected first, TONOPORT V version 2.0 and later, and TONOPORT VI devices will automatically copy that patient ID number from the CardioSoft database.

5 

Click to download the stored data to the system.

6 

Click to delete the data stored in the ambulatory blood pressure monitor.

7 

Click to load system setups stored for different system users.

8 

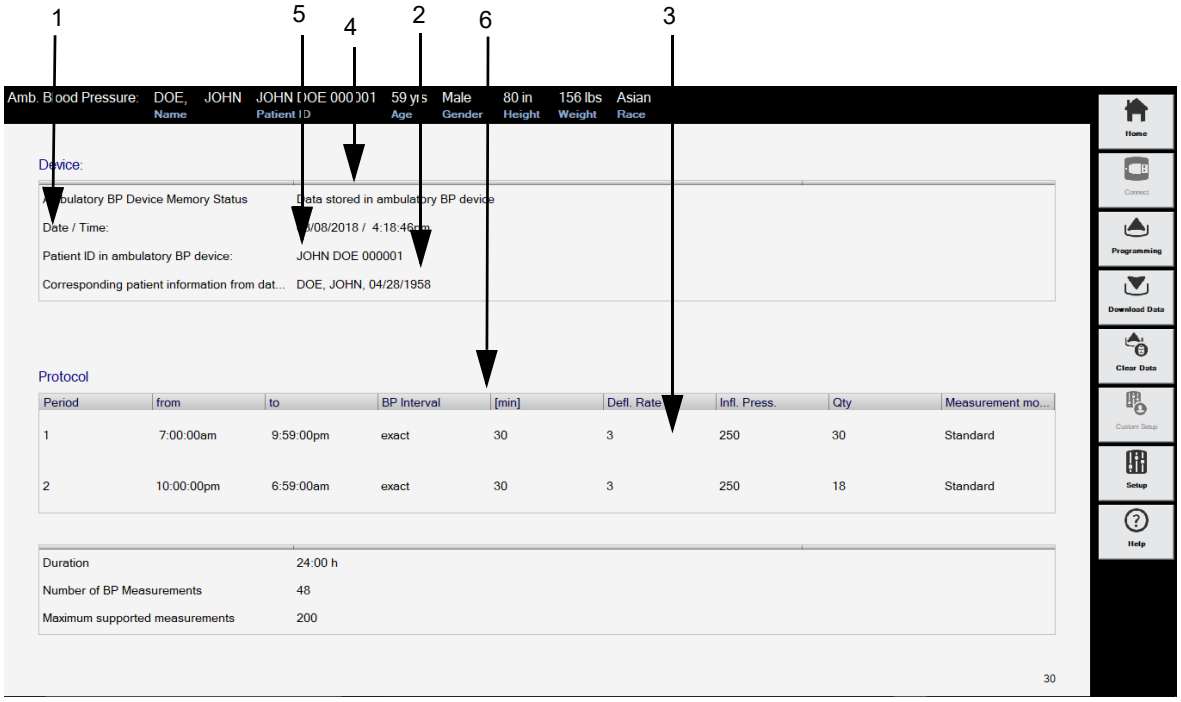
Click to display the setup menu for ambulatory blood pressure measurements. (see "Ambulatory Blood Pressure Measurement for example," on page 12-31).

9 

Click to activate the online help program.

Operating Steps

The acquisition screen indicates the memory status of the ambulatory blood pressure monitor.



1 Date and time of the monitor.
2 Measurement protocol.

3 Number of BP measurements and the duration of the protocol.

4 Information if the data is stored in the monitor.

5 Patient ID stored in the TONOPORT device.

6 Patient data from the CardioSoft database assigned to the patient ID.

To operate the TONOPORT device, perform the following steps:

1. Turn the monitor off and on.
2. Wait for the time to be displayed, and then connect the monitor to the PC.
3. Click *Connect*.
4. Click *Clear Data* to delete data stored in the monitor (with TONOPORT V version 2.0 and later, and TONOPORT VI, this command will also clear the patient ID).

   Note

   If the stored data has not been transferred to the system, download it as described in the next section.

5. Click *Programming* to select the protocol. You can choose between two protocols.

   Note

   If you are using TONOPORT V version 2.0 and later, and TONOPORT VI, check the displayed patient data to avoid data mismatch.

6. Turn the monitor off and disconnect it from the PC.
7. Connect the monitor to the patient (see TONOPORT Operator's Manual).

Post Test Review

Downloading Data

1. Turn the monitor off and on.
2. Wait for the time to be displayed, and then connect the monitor to the PC.
3. Select the patient.

   Note

   If the patient ID has been stored in TONOPORT V version 2.0 and later, and TONOPORT VI, you are not required to select the patient. Click *Select* and you will see the acquisition screen.

   Be sure to download the data to the same database from which you read the patient ID.

   The TONOPORT VI device functionality might read up to 400 measurements.

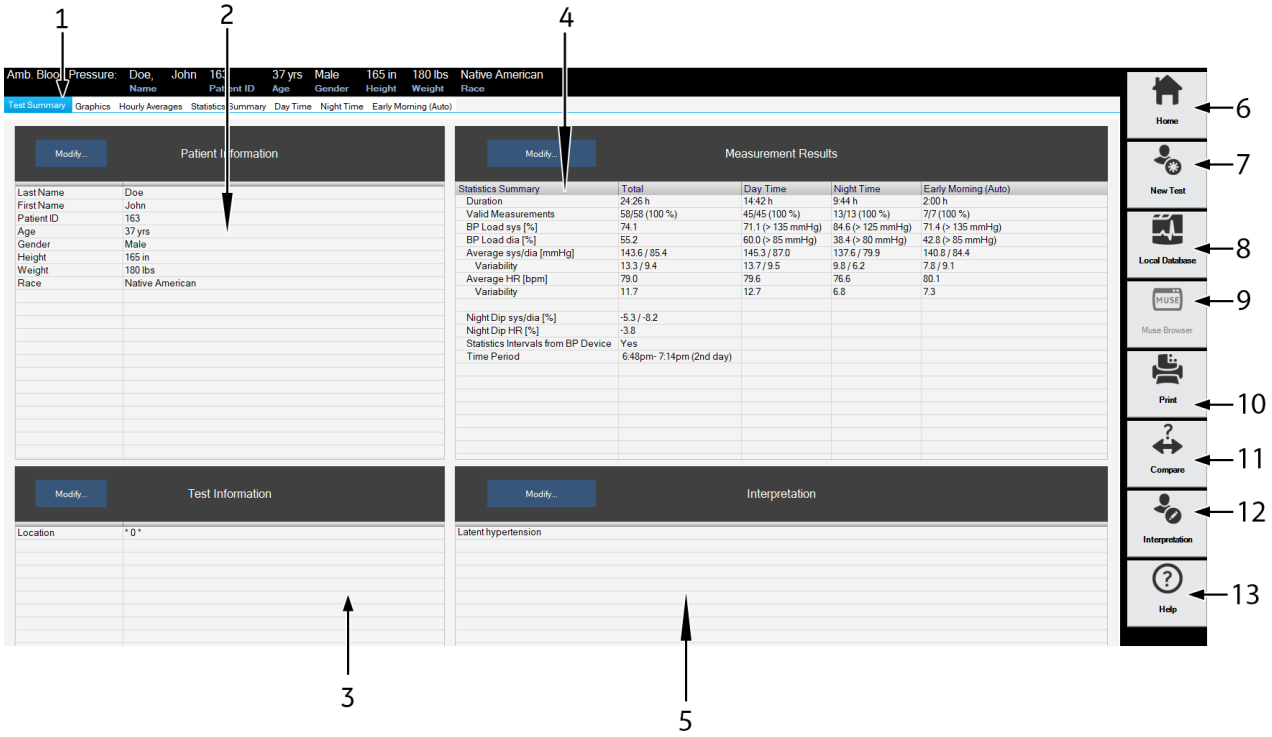
4. Click *Connect*.
5. Click *Download Data*. After the download, the *Test Summary* tab opens.

   Note

   Do not forget to delete the data stored in the monitor. This is to ensure that the monitor does not contain data from a previous test when used on a new patient.

   When the message *Inconsistent data in ambulatory BP device! Procedure cannot be saved!* displays, turn the monitor off and on.

Test Summary



1 *Test Summary* tab.

2 Patient Information.

3 Test Information.

4 Measurement Results.

5 Physician's interpretation.

6 

Click to return to the Home screen.

7 

Display patient list for a new test.

8 

Display a list with current patient tests in the local database.

9 

View patient tests from MUSE database.

10 

Open the print for example, window.

11 

Display the comparison data of the selected items graphically and numerically.

12 

Open the interpretation window.

13 

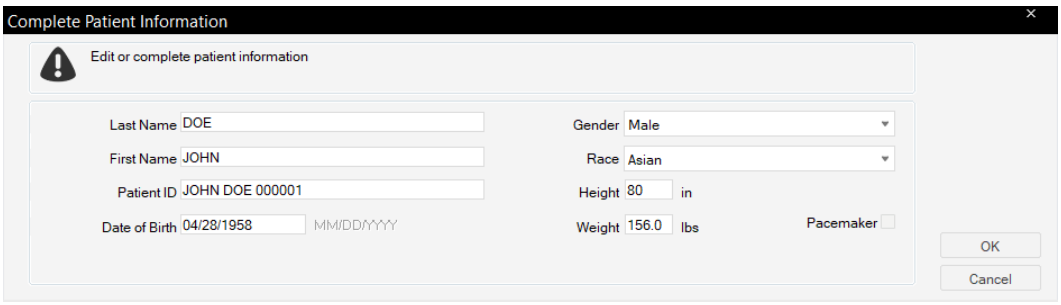
Open Help.

Click *Modify* edit or complete the data.

Patient Information

You can edit or complete the data. Any changes you make will be assigned to this procedure, not to the patient.

The Patient Information can be assigned to the patient file or to the pending test.

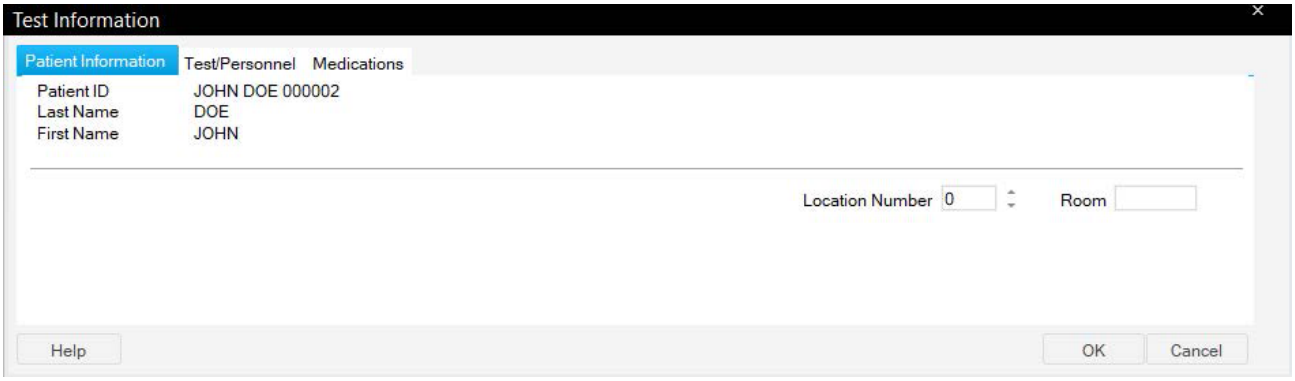


Test Information

At the *Test Information* window, you can enter or edit the following:

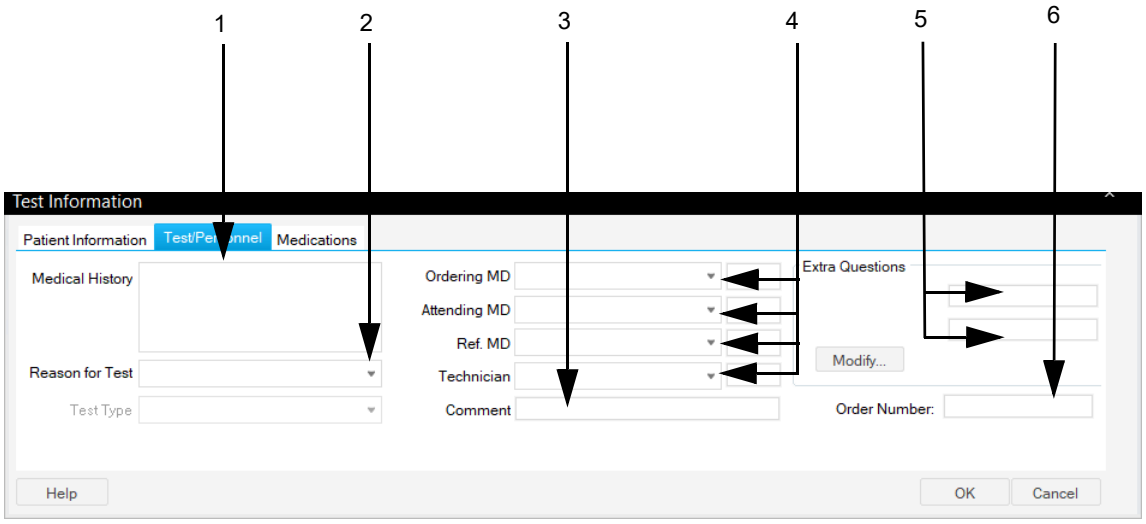
- *Patient Information*
- *Test/Personnel*
- *Medications*

Patient Information



The changes you make will be assigned to this procedure, not to the patient.

Test/Personnel



1 From the *Test/Personnel* tab, enter the relevant information in the *Medical History* field.

2 Enter or select the *Reason for Test*. Multiple selections are permitted.

3 Type or select the physician's and technician's names.

4 Type any *Comment* about the test.

5 Answer the *Extra Questions*.

6 Enter an *Order Number*. This number will appear on the printed reports and on the Test Summary.

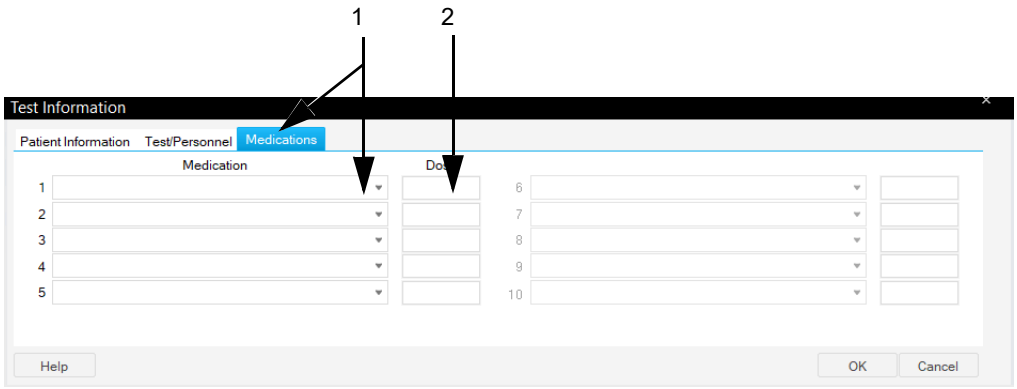
Note

You can edit the *Reason for Test* list (see "Miscellaneous Tab" on page 12-22).

You can define two Extra Questions.

You enter the names of the physicians and of the technician in the System Configuration (see "General Tab" on page 12-35).

Medications



1 From the ***Medications*** tab, enter or select up to five medications.

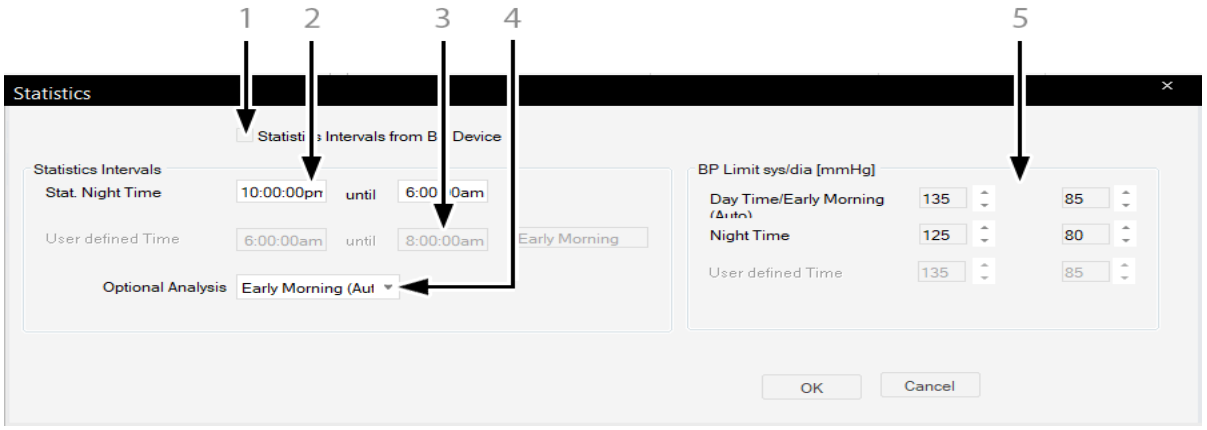
2 Enter the medication dose.

Note

You can edit the medication library.

Measurement Results

Modify the statistics intervals and the blood pressure limits for this report.



1 Enable to perform the statistical analysis with the statistics intervals from the ambulatory BP device. If not enabled, the default system intervals will be used. See "Editing the BP Protocol" on page 12-21. The check box is accessible only when 1 or 2 BP periods are selected at the TONOPORT V version 2.0 and later, and TONOPORT VI.

2 Change the statistical night time.

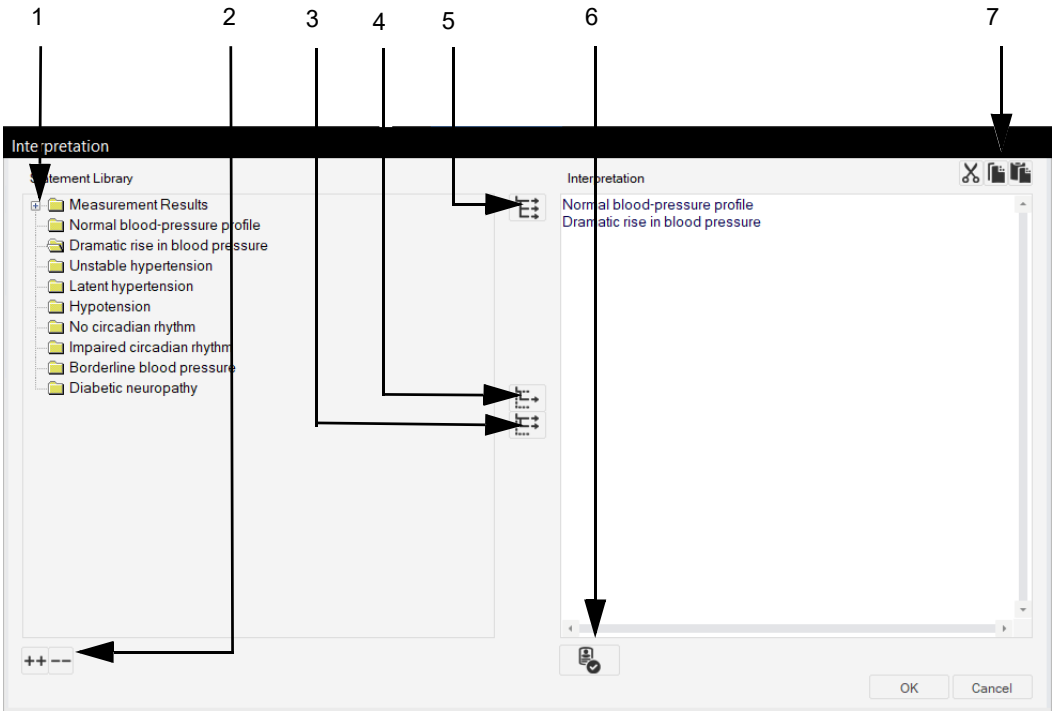
3 Select the *Optional Analysis* from the drop-down list:
- *None*
- *User defined*
- *Early Morning (Auto)*.

4 Change the user-defined time. This field is enabled if you select *User defined* from the *Optional Analysis* drop-down list.

5 Configure the BP Limits.

Generating or Editing the Interpretation

Click *Interpretation* or *Modify...* to open the *Interpretation* window. The Statement Library lists the folders with standard interpretation text. You can create an interpretation by creating standard text which you can copy to the Interpretation area. In the Interpretation area you can edit the text (enter new text, copy, cut, paste, and so on.). See "Editing the Interpretation Library" on page 12-4 for information on editing standard text.



1		Click to open folders individually.
2		Click to simultaneously open (++) or close (--) all folders.
3		Click to copy branch.
4		Click to add individual line.
5		Click to add line and chapter.
6		Click to confirm the test results.
7		Click to cut, copy, and paste text in the interpretation area.

Note

You can also double-click the text to copy it.

Graphics

The *Graphics* screen displays all blood pressure values acquired over the monitoring period. The blood pressure values are shown at the top, the pulse pressure values (systolic pressure minus diastolic pressure) below. You can show or hide the pulse pressure values (see "Miscellaneous Tab" on page 12-22).

You can choose between display formats 1, 2 and 3. This format can be preset in the System Settings and is saved as a user-specific configuration. The selected format will also be used for print-outs.

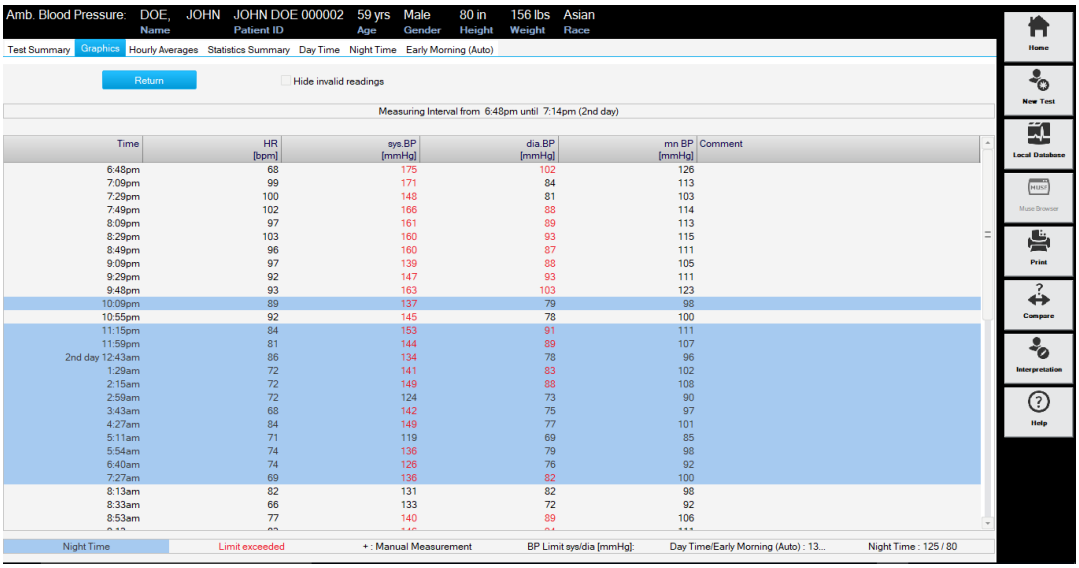
A small window with the values corresponding to the measurement will be displayed as you move the mouse over the diagram.



1 Click the tab to display the corresponding window.
2 Click to display the tabular summary.
3 Displays measurements at the cursor position.
4 Zooms the measured values in or out.
5 Click the arrows to move to next page and previous page.

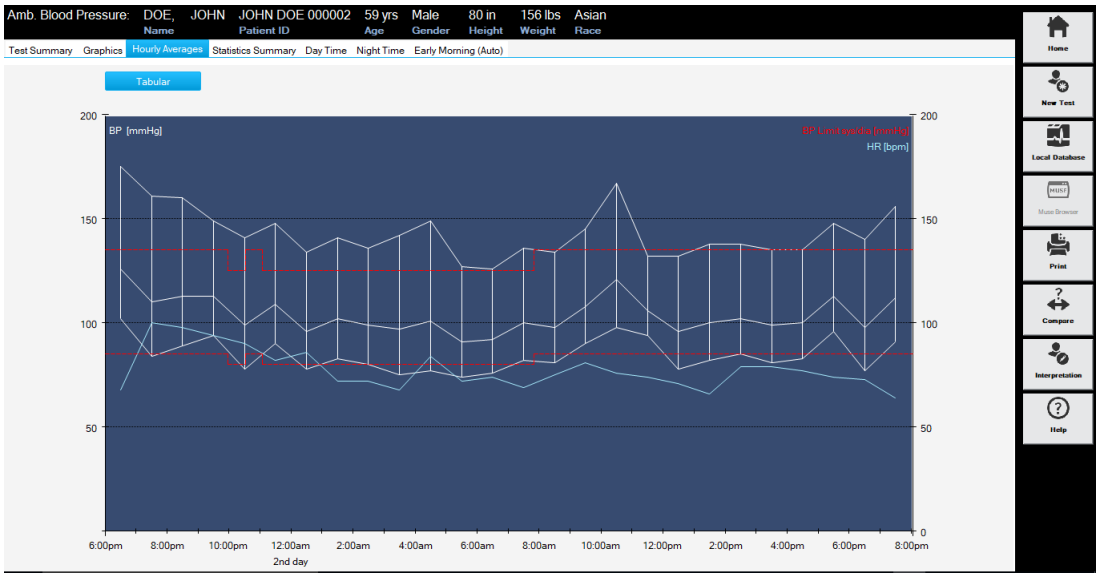
Tabular Summary

Displays individual measurements. Suppressed measurements are excluded from the statistical analysis.



Hourly Averages

Displays the *Hourly Averages* of all measurements taken during the monitoring period. Click *Tabular* to view the same values in tabular format.



Statistics Summary

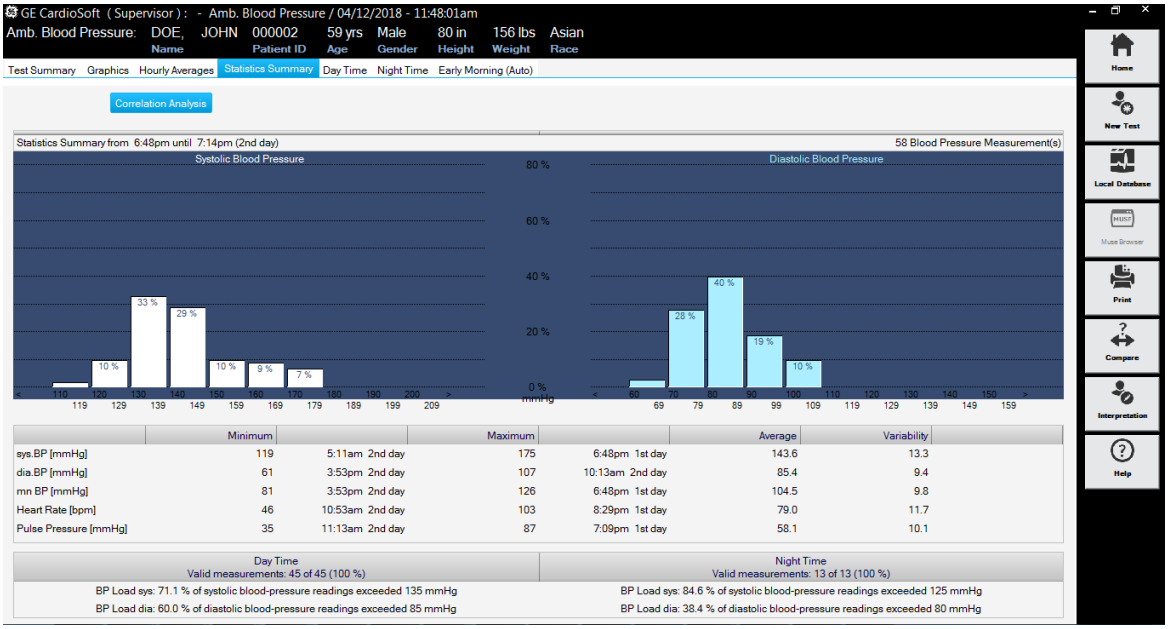
Displays one histogram each for the systolic values (left) and the diastolic values (right), and the frequency distribution given as a percentage.

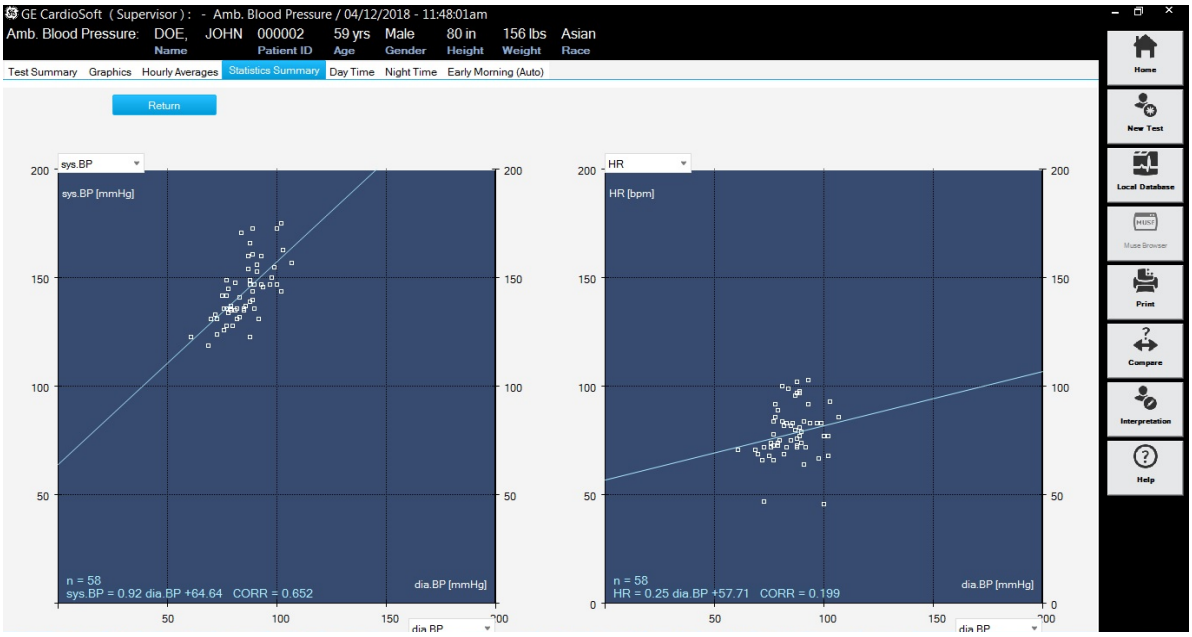
The table displays the maximum, minimum, mean values, and the standard deviations. The percentage of readings that exceeded the set limits is shown at the bottom.

The *Correlation Analysis* tab displays two graphs, each graph presents an analysis report of correlation between two parameters. The parameters are; *HR*, *sys.BP*, *dia.BP*, *mn BP*, and *Pulse Pressure*.

You can select the desired parameters in the drop-down list of graphs.

Similar report pages exist for the *Day/Time, Night/Time,* and the *Early Morning (Auto)* tabs.





Compare

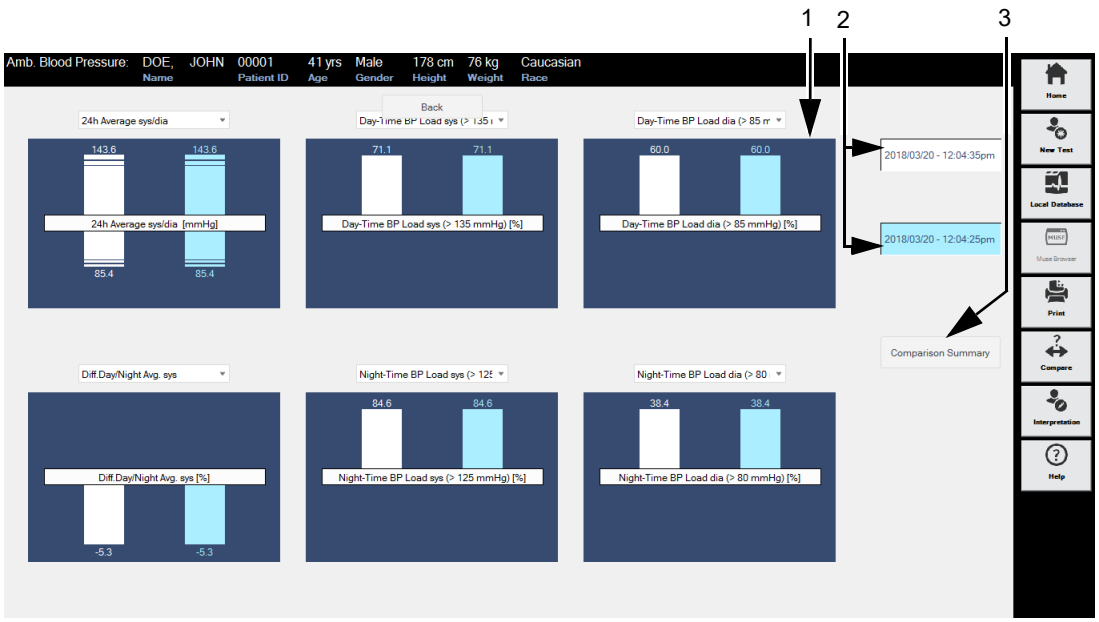
Displays the comparison graphs for the following parameters:

- *24h Average sys/dia [mmHg]*
- *Day-Time BP Load sys (> 135 mmHg) [%]*
- *Day-Time BP Load sys (> 85 mmHg) [%]*
- *Diff Day/Night Avg sys [%]*
- *Night-Time BP Load sys (> 12 5 mmHg) [%]*
- and *Night-Time BP Load dia (> 80 mmHg) [%].*

1. Click *Compare*.
2. In the *Compare Test* screen, select the reports you want to compare.

   Up to four reports can be selected for comparison.
3. Click *OK*.

   Comparison graphs of the selected reports are displayed. To view a comparison summary of the selected reports, click *Comparison Summary*. A comparison summary displays the test information and interpretation of the selected reports.



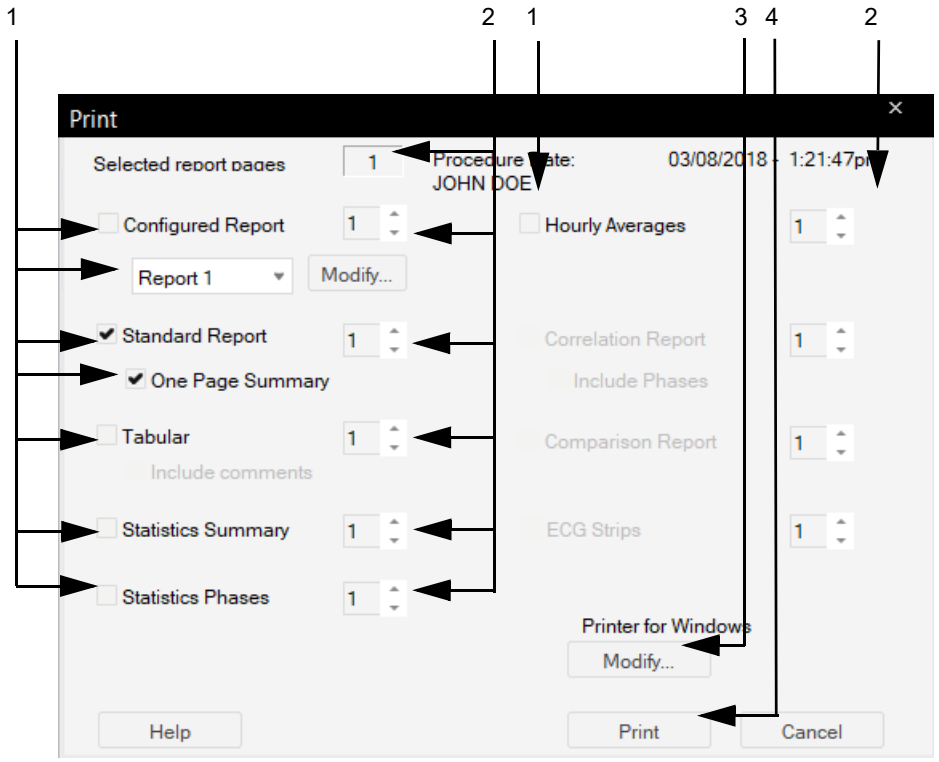
1 Date and time of each report used in the comparison.

2 Comparison graph.

3 Comparison summary.

Printing the Report

Click *Print* to print the report. The print for example, window opens where you can temporarily adjust the settings for the printout. See"Miscellaneous Tab" on page 12-22 for details on changing the for example, permanently.



1 Select the check box to include the documents into report:
•Standard page (Test Information, Statistics Summary, Graphics).
•Tabular (All measured values in tabular format).
•Statistics Summary (Statistics summary, but divided into day time, night time, and early morning).
•Statistics phases (Same as statistics summary, but divided into day time, night time, and early morning).
•Configured Report (To choose the report format, click on modify > to display the report editor).
•Hourly Averages (Tabular and graphics format).

2 Select the number of copies to print.

3 Click *Modify* to select the printer.

4 Click *Print* to initiate the printout.

8 Spirometry Test

For your notes

For information on intended use, refer to Spiro-SP TrueFlow™ Sensor Instructions for Use.

DANGERS

EXPLOSION HAZARD — The TrueFlow Sensor is not designed for use in areas of medical locations where an explosion hazard may occur. Explosion hazards may result from the use of flammable anesthetics, skin cleansing agents or disinfectants. Great care must be exercised when the system is used in an oxygen-enriched atmosphere. The atmosphere is considered to be oxygen-enriched when the room air contains more than 25% of oxygen or nitrous oxide.

PATIENT HAZARD — Observe the following points when performing bronchial provocation tests:

- Bronchial provocation tests can be dangerous for patients. Bronchial provocation test procedures must be performed under the direct supervision of a trained and experienced physician.
- Physicians must be familiar with appropriate precautions and guidelines, warnings, procedures, contraindications, when to stop further testing, etc. as defined in the medication documentation and in the standards.
- Observe the contraindications for the medication used, such as:
    - General clinical instability of the patient.
    - Severely reduced lung function.
    - Treatment with beta blockers.
    - Hyperresponsiveness.
    - Pregnancy.
- A physician or specially trained staff must be present while bronchial provocation tests are being performed. The patient should never be left unattended during the tests.
- The following should be available throughout the duration of the provocation tests:
    - A medical specialist capable of treating acute bronchospasm.

- Appropriate medication as well as resuscitation equipment (defibrillator, cardiac pacemaker).

- Refer to the relevant literature for creating safe protocols for bronchial provocation tests.

Warning

Devices may be connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the operators, or the environment as a result. In those instances, where there is any element of doubt concerning the safety of connected equipment, the user must contact the manufacturers concerned or other informed experts to find out whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of equipment. Standards IEC 60601-1-1/ EN60601-1-1 must be complied with in all cases.

Before using the device, the operator must ascertain that it is in correct working order and operating condition. The cables, in particular, must be checked for signs of damage. Damaged cables and connectors must be replaced immediately, before use.

Liquids must not be allowed to enter the TrueFlow Sensor or the PC. Devices into which liquids have entered must immediately be cleaned and checked by a service technician, before they can be reused.

PATIENT HAZARD — The operator must be trained in the use of the device.

PATIENT HAZARD — Before performing any tests on patients, refer to the ATS/ERS Taskforce recommendations.

PATIENT HAZARD — User-configured printouts bear the label “Custom Report”. The user is entirely responsible for the design, content and use of the printouts.

RISK OF INFECTION — Follow all cleaning procedures carefully, and thoroughly inspect the components after they are cleaned and before each patient is tested. Cleaning residue, particulate matter, and other contaminates (including pieces of torn or broken components) in the breathing circuit create a safety risk to the patient during test procedures. Aspiration of contaminates can be potentially life-threatening.

RISK OF INFECTION — Proper use of the spirette

provides a reliable infection barrier. The use of other accessories is not permitted.

CROSS-CONTAMINATION BETWEEN PATIENTS — The spirette is intended for single-patient use. Use a new one for each patient to prevent cross contamination between patients.

SUFFOCATION HAZARD — Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packaging material out of children's reach.

Note

Adobe Flash player must be installed in the system to use Spirometry.

Spirometry Test

Spirometry is the most common lung function test. It measures how much and how quickly you can move air out of your lungs. You breathe into a mouthpiece attached to a machine called a spirometer. The machine records your results.

Spirometry can measure different parameters about the way you breathe. These include how much air you can exhale, how much air you can breathe in and out in 1 minute, and the amount of air left in your lungs after a normal exhale.

Spirometry tests are designed to identify and quantify defects and abnormalities in the function of the respiratory system.

Test Types

The following spirometry test types can be enabled in the system:

- Forced Vital Capacity (FVC)
- Flow-Volume loop (FVL)
- Maximal Voluntary Ventilation (MVV)
- Slow Vital Capacity (SVC)

To configure the available test types and other parameters related to the spirometry tests, see section "Acquisition Tab" on page 12-24.

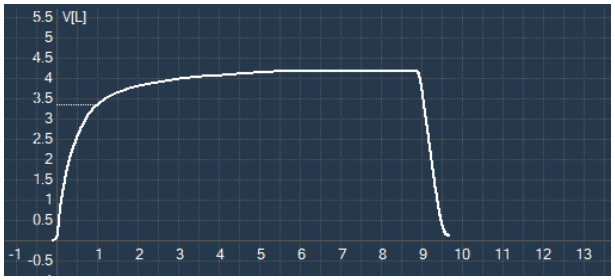
Forced Vital Capacity (FVC)/Flow Volume Loop (FVL)

Forced Vital Capacity (FVC) and Flow Volume Loop (FVL) measure the rate at which the lung changes volume during forced breathing procedures. FVC/FVL measures the dynamic volume of the lungs. The patient inhales maximally and then exhales as rapidly as possible.

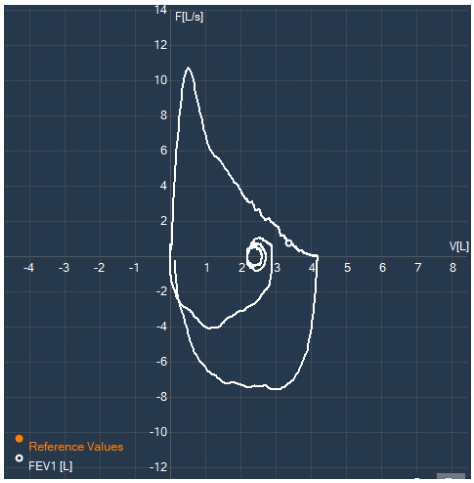
FVC/FVL displays a Flow-Volume and Volume-Time graph.

Abnormalities can cause decreases in FVC/FVL.

The following graph displays an example of volume-time and flow-volume test results:



Volume-time



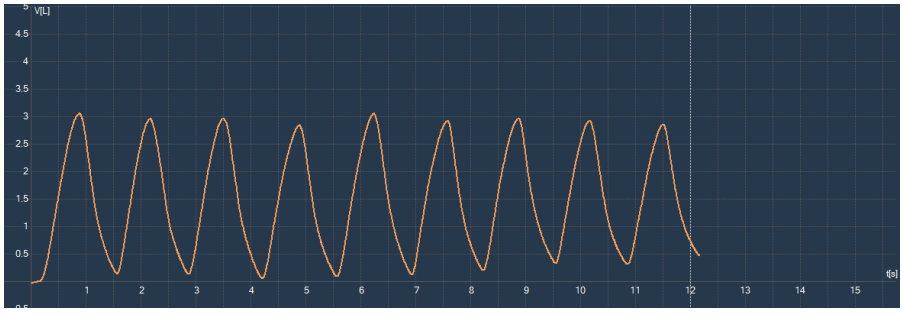
Flow-volume

Maximal Voluntary Ventilation (MVV)

During a Maximal Voluntary Ventilation (MVV) test, the patient is instructed to breathe as hard and fast as possible for 10 to 15 seconds.

A low MVV can occur in obstructive diseases.

The following is an example of an MVV test result:

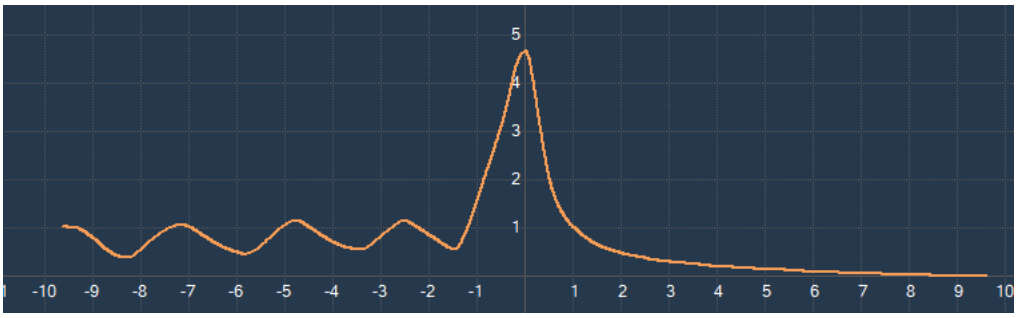


Slow Vital Capacity (SVC)

Slow Vital Capacity (SVC) measures static lung volume.

The vital capacity (VC) is measured by having the patient inhale maximally and then exhale slowly and completely. The VC is called the slow vital capacity (SVC). The difference between SVC and FVC reflects trapping of air in the lungs.

The following is an example of SVC test result:

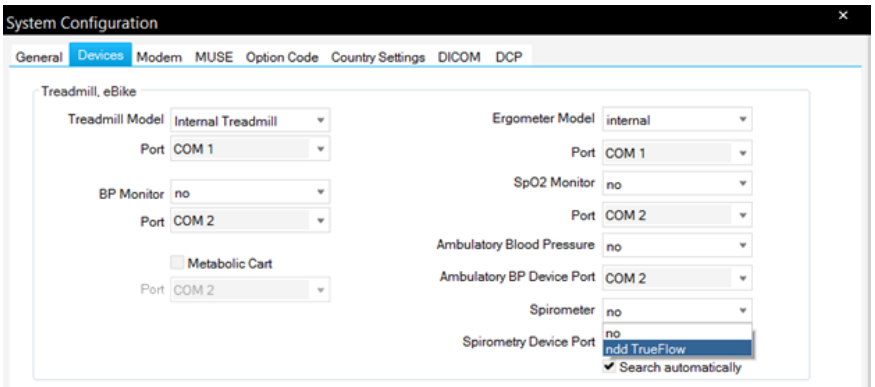


Preparing the Spiro-SP TrueFlow™ Sensor

For information on preparing the Spiro-SP TrueFlow Sensor, see Spiro-SP TrueFlow Sensor Instructions for Use.

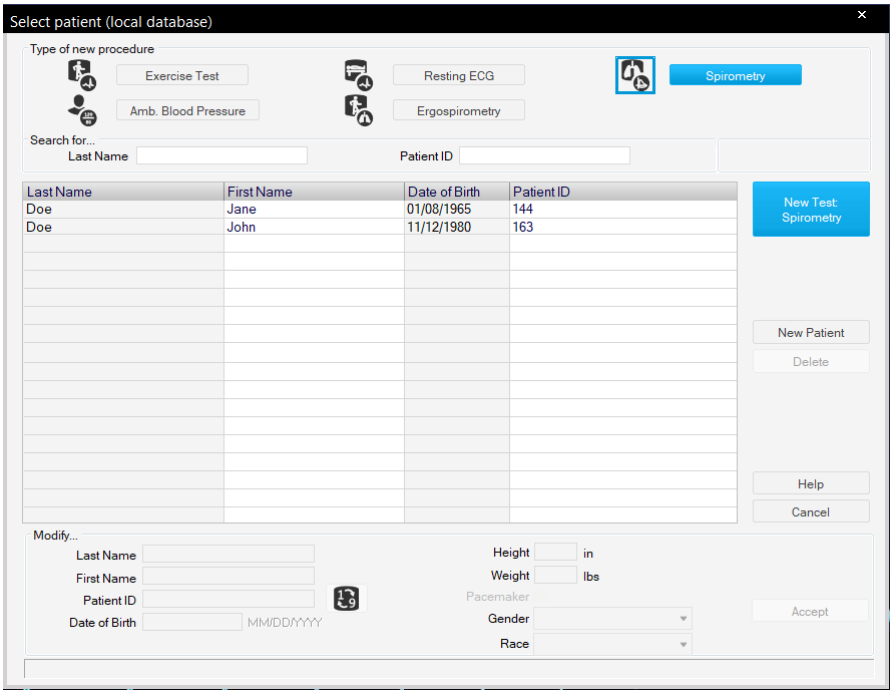
Configuring the System for the TrueFlow Sensor

1. Connect the TrueFlow Sensor to the USB port.
2. From the *System Configuration* window, select the *Devices* tab.
3. From the *Spirometer* list, select *ndd TrueFlow Sensor*.
4. From the *Spirometry Device Port* list, select the port that connects to the spirometer.

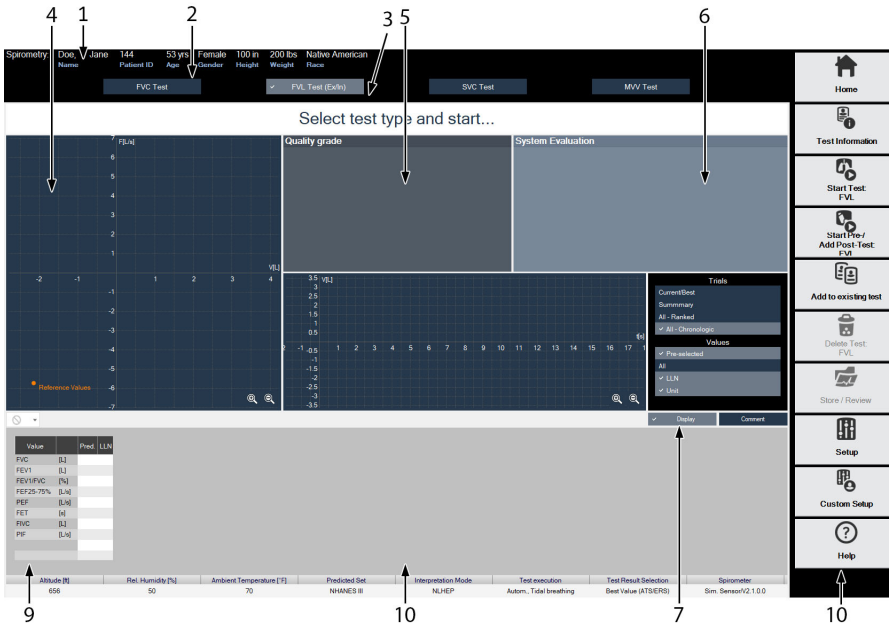


Entering Test Information

1. Click *New Test*. The *Select / Create Patient* screen appears.



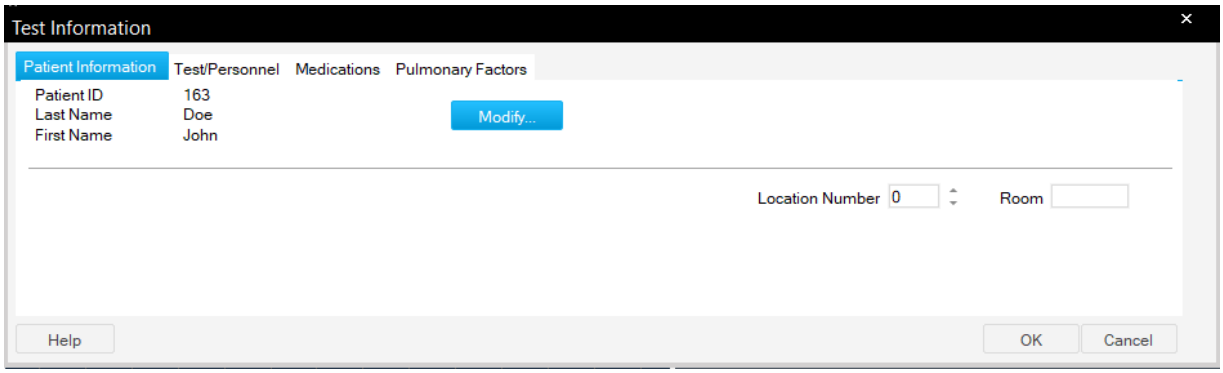
2. Click *Spirometry,* select a patient, and then click *New Test Spirometry*. The acquisition screen opens.



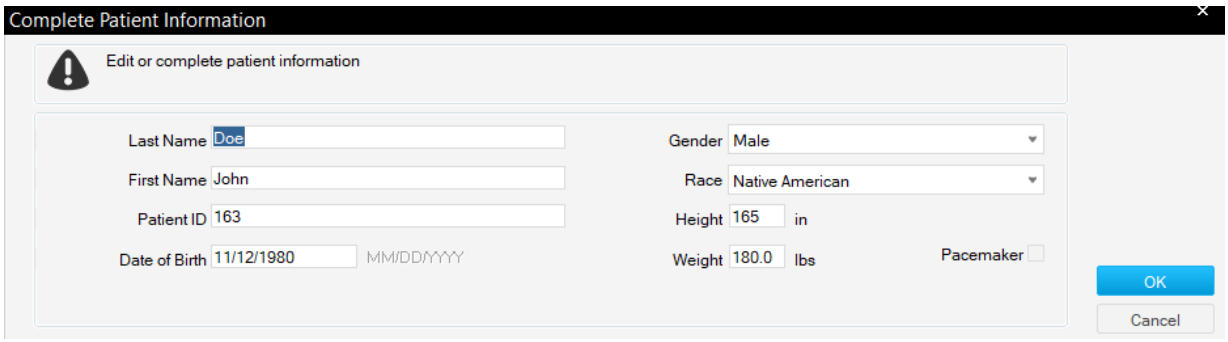
3. Click *Test Information* to enter the test details.

Entering Patient Information

From the *Patient Information* tab, verify the patient's name and ID.



Click *Modify* to edit the patient information.



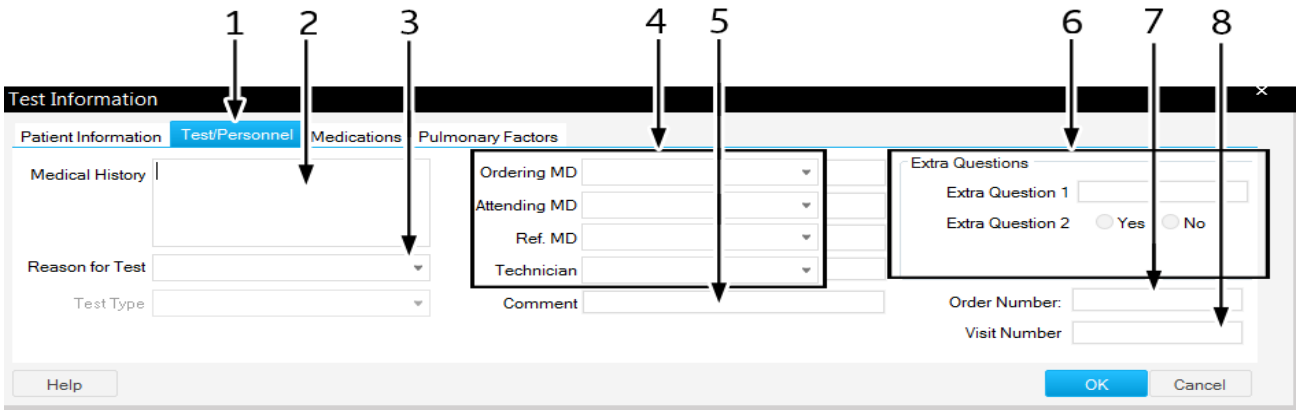
Note

Depending on the selected reference value equation, the program requires the gender, height, weight, date of birth, and race data for calculation of the spirometry reference value (see section "Spirometry Reference Value Equations, Interpretation Modes, Measurements" on page B-11).

You can assign a location name to the location number (see section "MUSE Tab" on page 12-44).

The Patient Information can be assigned to the patient record or only to the pending test.

Entering Test/Personnel Information



1. Test/Personnel tab.
2. Medical History information.
3. Select the Reason for Test. Multiple selections are permitted.
4. Select or enter the physician's and technician's names.
5. Comment.
6. Extra Questions.
7. Order Number displays on the printed reports and on the Test Summary.
8. Enter the Visit Number, if it was enabled in the System Configuration (see section "Country Settings Tab" on page 12-46). This number will appear on the printed reports and on the Test Summary.

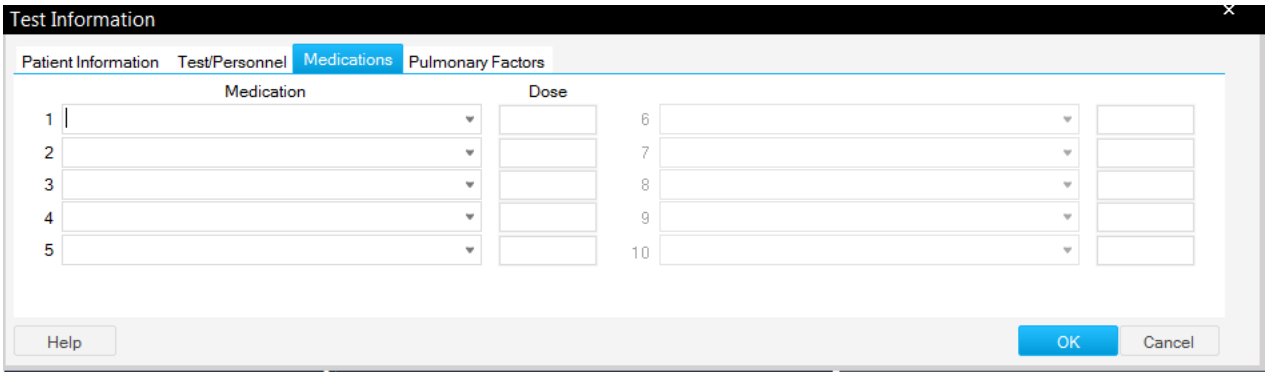
Note

The *Reason for Test* library can be edited (see section "Editing the Interpretation Library" on page 12-23).

You can define two Extra Questions as needed (see section "Miscellaneous Tab" on page 12-26).

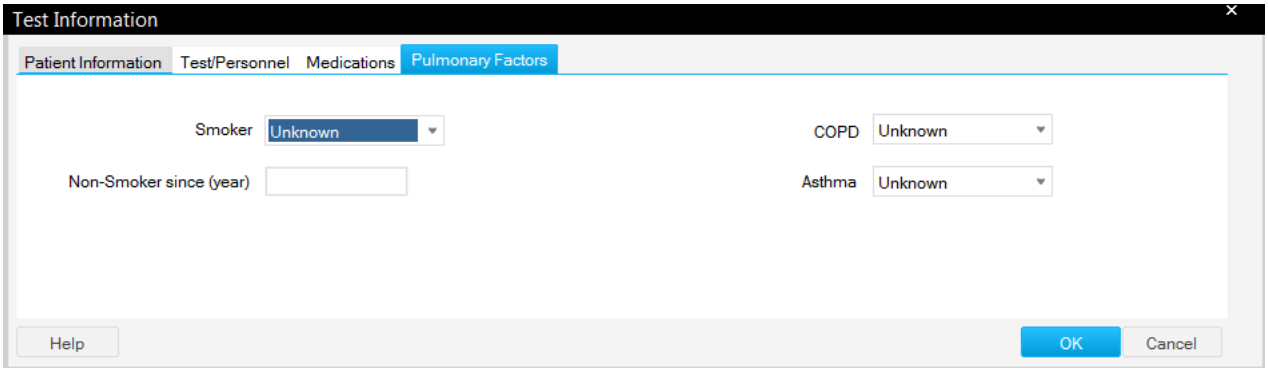
You enter the names of the physicians and of the technician in the System Configuration (see section "General Tab" on page 12-35).

Entering Medications Information



1. Click *Medications*.
2. Enter up to five medications and the dose.

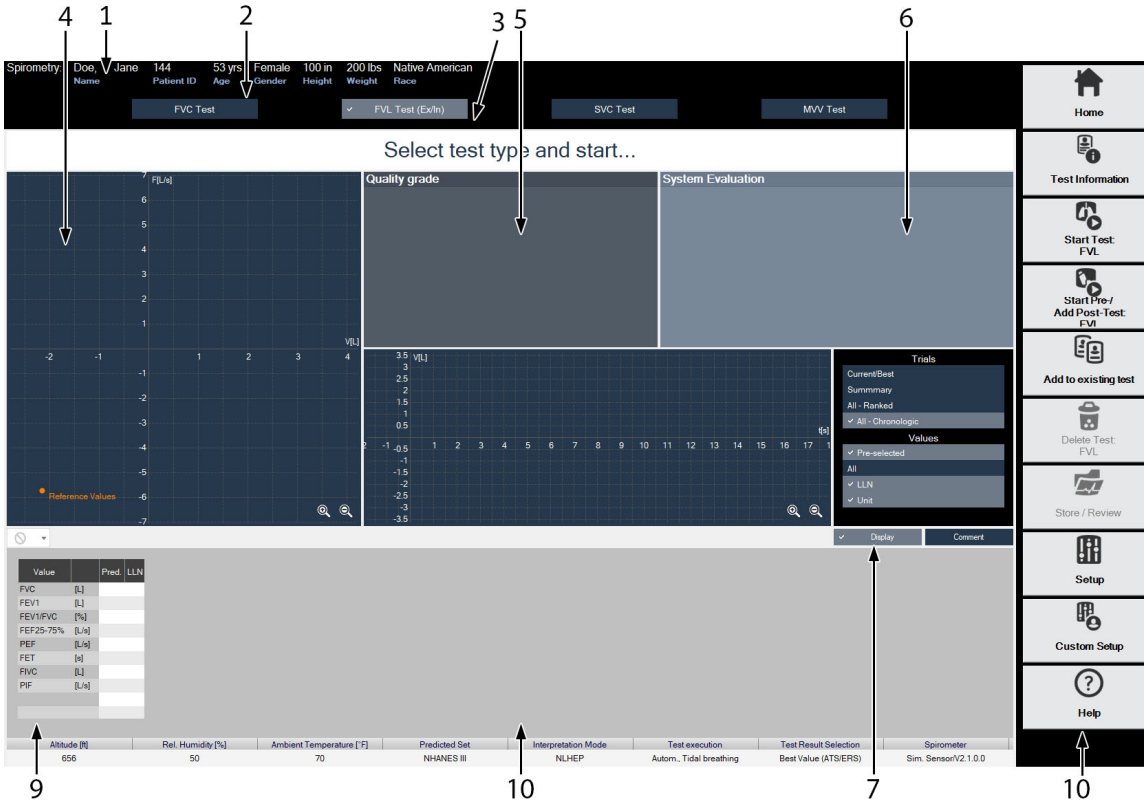
Pulmonary Factors



1. Click *Pulmonary Factors*.
2. Enter the Smoker status, if known.
3. Enter the COPD status, if known.
4. Enter the Asthma status, if known.

Conducting a Spirometry Test

The following figure illustrates the Spirometry test screen:



Note

The graph can be maximized/minimized by double-clicking on the graph.

1	Patient Information
2	Test Type
3	Tool Tip, displaying test procedure
4	Graph Area
5	Quality Grade
6	System Evaluation
7	Settings for Trial display/Adding comments (current time can be added)
8	Spirometry Test Tool Bar
9	Trials Data
10	Test information

Note

You can right-click on the patient information and select settings to edit the font size and style. When display settings are changed in application, it is advised to restart the application.

Preparations

Caution
RISK OF INJURY — Pulmonary function tests require maximum effort on the part of the patient and may lead to dizziness.

RISK OF INFECTION — The spirette is designed for single use. Use a fresh spirette for each new patient.

RISK OF INFECTION — In settings where tuberculosis or other diseases that are spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration or ultraviolet decontamination of air, should be used to prevent disease transmission.

The patient should be relaxed and not wear any tight clothing. The patient may stand or sit during the test. The patient may feel dizzy when performing the test, therefore, watch your patients closely if they are standing for the test.

Explain that the purpose of the test is to determine how much air a person's lungs can hold and how quickly that air can be exhaled. A spirometry test requires active participation by the patient, it is important to explain the test procedure:

1. The spirette goes in the patient's mouth with the lips sealing it. Make sure not to block the opening with the tongue or bite down excessively.
2. Breathe calmly.
3. Fill lungs completely.
4. Exhale as fast and as deeply as possible.
5. Continue blowing out until the lungs are completely empty.
6. Breathe in again.

If you are new to spirometry, practice testing on yourself prior to testing on patients. You will learn to recognize the cause of problems by interpreting the Quality Messages displayed by the program after each trial and how to avoid these problems.

After a poor trial, explain to your patient how to improve the procedure.

Performing the Measurement Test

1. Insert the new spirette in the sensor.
2. Attach the nose clip to the patient.
3. Select the type of test you want to perform on the patient:

- FVC Test
- FVL Test (Ex/IN)
- SVC Test
- MVV Test

4. Click *Start Test: <Test_Name>* in the Spirometery test screen to start the selected test. *<Test_Name>* is the type of test you selected.

It is recommended the spirette closed until the test start prompt is displayed. This is necessary to set the correct baseline.

Note

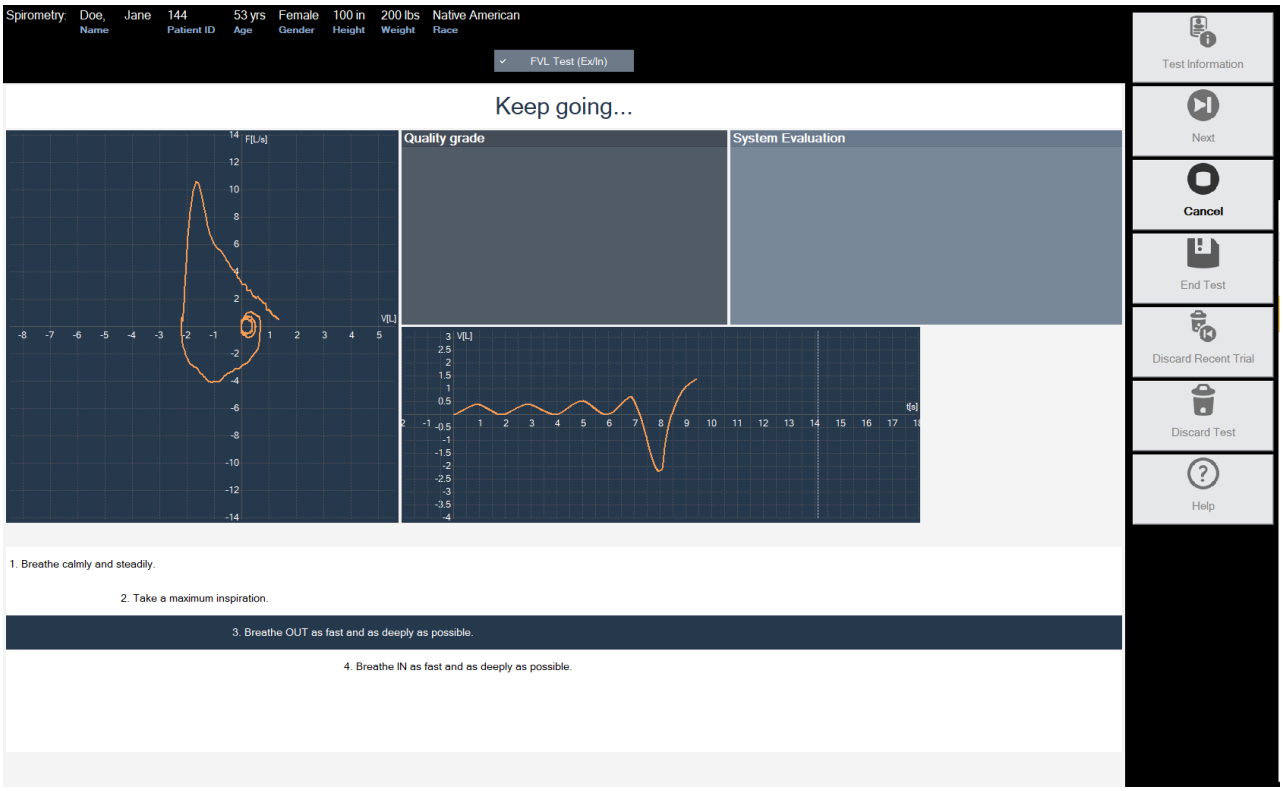
It is recommended to remove the rest of the spirette packaging which wraps the mouthpiece and keep it closed only after the baseline has been set.

5. Keep the spirette closed on one end and confirm the message.
6. When the start test prompt is displayed, hand the sensor over to your patient and instruct the patient to perform the procedure. The default ambient conditions display.
7. Select the required values and click *OK*.

Note

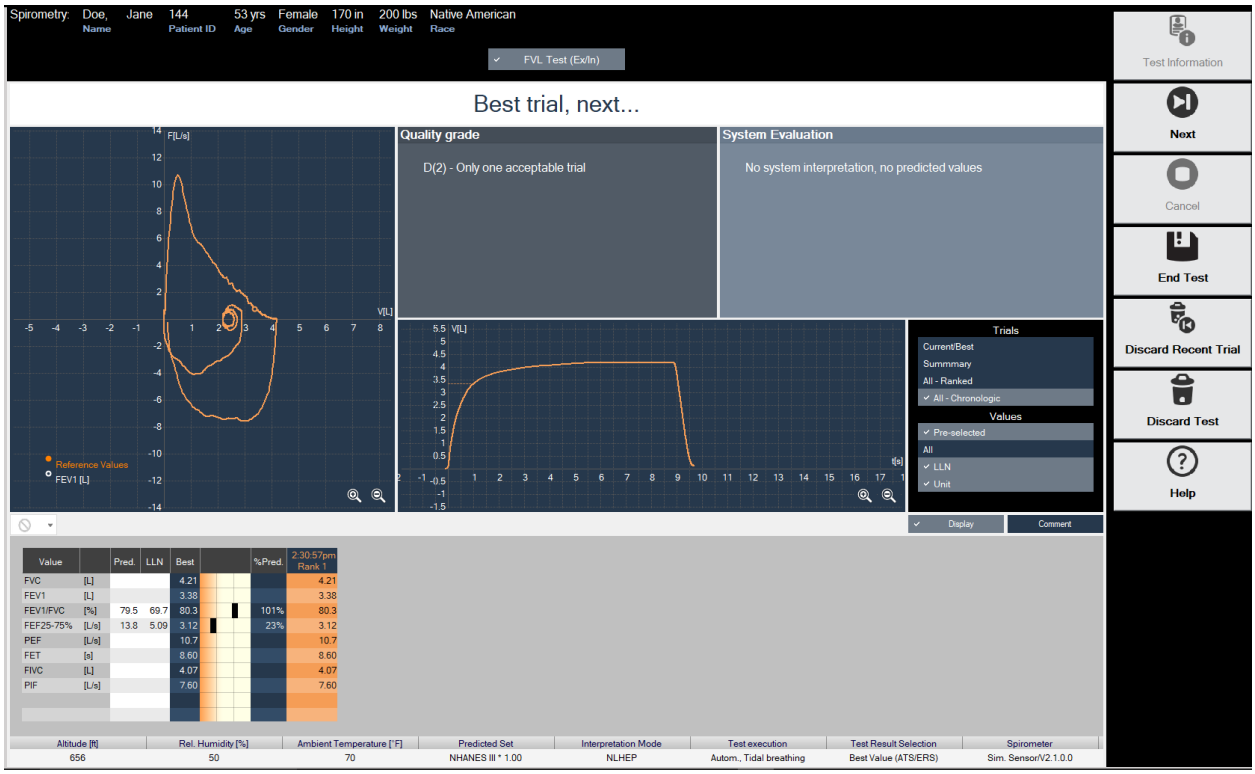
When the Spirometry new work flow test is started, amplitude and baseline settings are performed as part of the preparation steps, to make sure that the signal is optimal range and zero flow is correct. Once these preparation steps are completed, sensor uses the configured trigger volume and flow start limit to determine TIMEZERO (start of test/Inspiration/Expiration).

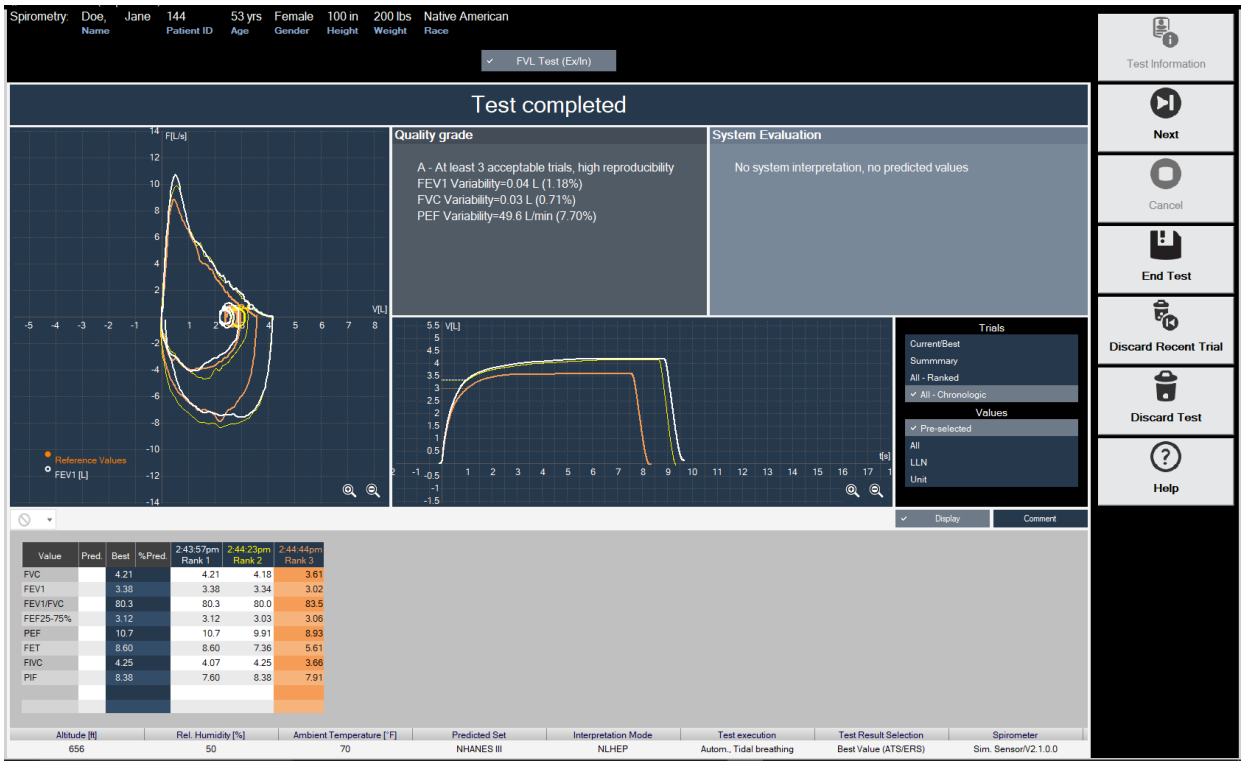
The screen displays step-by-step breathing instructions to the patient and display the graph:



Note

If the step-by-step breathing instructions are not clear, go to *System Configuration* > *Screen Diagonal* field to set the screen size per your display monitor. If required, you can also right-click on the instructions and go to *Settings* to edit the font size, type, and color of the instructions. Restart the application, if required.


Spirometry:
Doe, Jane
Name
144
Patient ID
53 yrs
Age
Female
Gender
170 in
Height
200 lbs
Weight
Native American
Race
FVL Test (Ex/In)
Best trial, next...
Quality grade
D(2) - Only one acceptable trial
System Evaluation
No system interpretation, no predicted values
Reference Values
FEV1 [L]
Trials
Current/Best
Summmary
All - Ranked
All - Chronologic
Values
Pre-selected
All
LLN
Unit
Display
Comment
Test Information
Next
Cancel
End Test
Discard Recent Trial
Discard Test
Help
Value
Pred.
LLN
Best
%Pred.
2:30:57pm Rank 1
FVC [L] 4.21 4.21
FEV1 [L] 3.38 3.38
FEV1/FVC [%] 79.5 69.7 80.3 101% 80.3
FEF25-75% [L/s] 13.8 5.09 3.12 23% 3.12
PEF [L/s] 10.7 10.7
FET [s] 8.60 8.60
FIVC [L] 4.07 4.07
PIF [L/s] 7.60 7.60
Altitude [ft] 656
Rel. Humidity [%] 50
Ambient Temperature [°F] 70
Predicted Set NHANES III * 1.00
Interpretation Mode NLHEP
Test execution Autom., Tidal breathing
Test Result Selection Best Value (ATS/ERS)
Spirometer Sim. Sensor/V2.1.0.0


Spirometry:
Doe, Jane
Name
144
Patient ID
53 yrs
Age
Female
Gender
100 in
Height
200 lbs
Weight
Native American
Race
FVL Test (Ex/In)
Test completed
Quality grade
A - At least 3 acceptable trials, high reproducibility
FEV1 Variability=0.04 L (1.18%)
FVC Variability=0.03 L (0.71%)
PEF Variability=49.6 L/min (7.70%)
System Evaluation
No system interpretation, no predicted values
Reference Values
FEV1 [L]
Trials
Current/Best
Summmary
All - Ranked
All - Chronologic
Values
Pre-selected
All
LLN
Unit
Display
Comment
Test Information
Next
Cancel
End Test
Discard Recent Trial
Discard Test
Help
Value
Pred.
Best
%Pred.
2:43:57pm Rank 1
2:44:23pm Rank 2
2:44:44pm Rank 3
FVC 4.21 4.21 4.18 3.61
FEV1 3.38 3.38 3.34 3.02
FEV1/FVC 80.3 80.3 80.0 83.5
FEF25-75% 3.12 3.12 3.03 3.06
PEF 10.7 10.7 9.91 8.93
FET 8.60 8.60 7.36 5.61
FIVC 4.25 4.07 4.25 3.66
PIF 8.38 7.60 8.38 7.91
Altitude [ft] 656
Rel. Humidity [%] 50
Ambient Temperature [°F] 70
Predicted Set NHANES III
Interpretation Mode NLHEP
Test execution Autom., Tidal breathing
Test Result Selection Best Value (ATS/ERS)
Spirometer Sim. Sensor/V2.1.0.0

During the FVC and FVL test, the flow-volume loop and the volume-time curve displays.

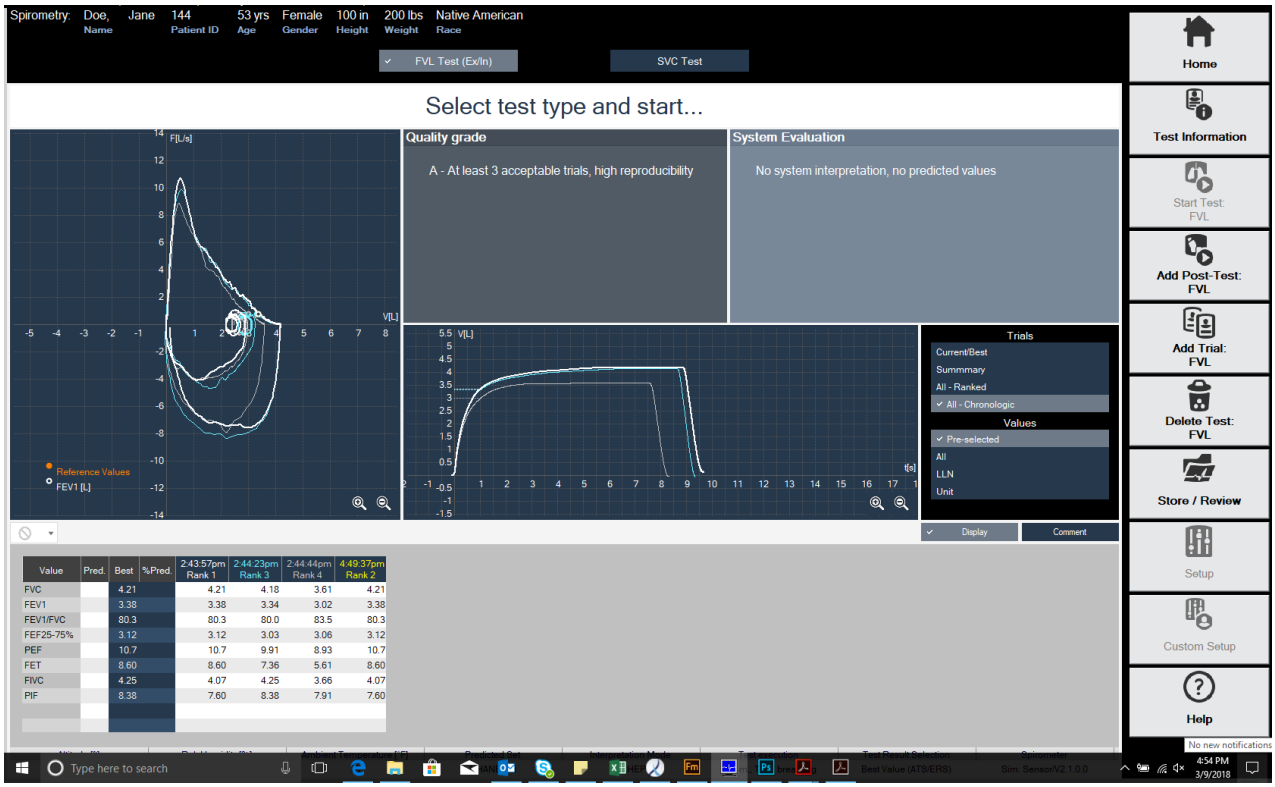
8. After the trial is complete, you can perform one of the following:
   - Click Next to record another trial.
   - Click Discard Recent Trial to discard the recent trial that you recorded.

You may stop measurements at any time. The measurements will remain stored.

If the trials have derived the expected test results, click *End Test* to end the test. The Spirometry test screen is displayed.

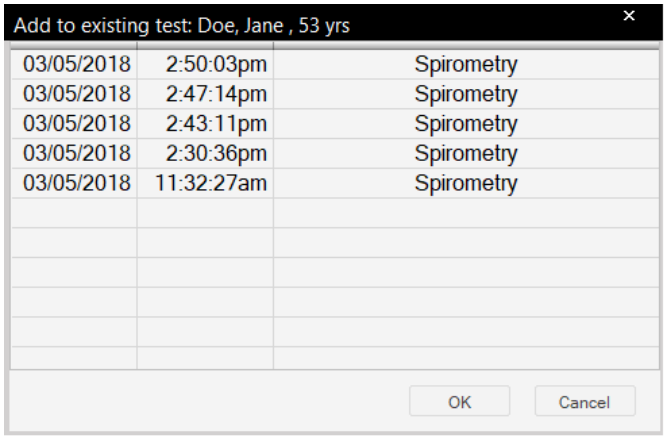
Note

If the *Manual Test Stop* is configured, click *End Test* or press the space bar or *Enter*.



9. Click *Add to existing test* to add the desired trials to the previous test.

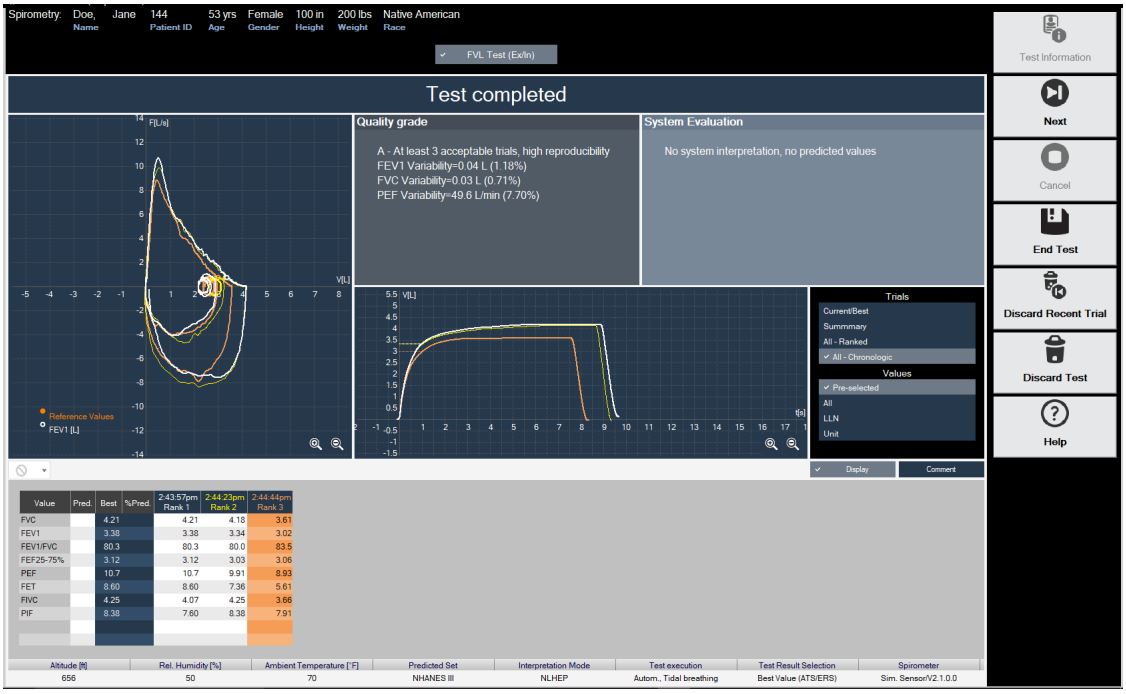
The list of trials is displayed.



10. Select the appropriate trial from the list.
11. Select *OK* to add the trial to the current patient test.

As soon as three or more acceptable tests have been performed, *Session Complete* is displayed along with a quality grade from A (optimal) to F.

Enter review comments or edit the results.



%Pred Graph

The %Pred Graph is a three-segment bar describing the values of tests taken as Rank 1, Rank 2, Rank 3, and so on.

Value		Pred.	LLN	Best		%Pred.	2:06:07pm Rank 1	2:06:33pm Rank 2	2:06:59pm Rank 3	2:07:29pm Rank 4
FVC	[L]	5.87	4.88	4.20		71%	4.17	4.20	3.78	3.78
FEV1	[L]	4.80	3.96	3.19		67%	3.19	3.14	2.91	2.91
FEV1/FVC	[%]	82.4	72.8	76.1		92%	76.6	74.8	77.1	77.1
FEF25-75%	[L/s]	4.82	3.12	2.56		53%	2.56	2.36	2.42	2.42
PEF	[L/s]	10.7	8.24	10.3		96%	10.3	9.84	9.25	9.25
FET	[s]			7.82			7.82	10.1	8.31	8.31

After ending of the test, push the spirette out of the sensor from the bottom. Dispose of the spirette and do not reuse.

For information on TrueFlow Sensor maintenance, cleaning and disinfection, see Spiro-SP TrueFlow Sensor Instructions for Use.

Ambient Conditions

The ATPS values (Ambient Temperature Pressure Saturated = spirometer conditions) of inspiratory measurements must be converted to BTPS values (Body Temperature Pressure Saturated = body conditions). For this conversion, the system needs the following data:

- Relative humidity.
- Room temperature.
- Atmospheric pressure or altitude.

Warning
ERRONEOUS MEASUREMENT RESULTS — Incorrect entries may lead to erroneous test readings and incorrect system interpretations. The specified measuring accuracy is ensured only when all entries are correct.

Bronchodilator (Test)

The test is usually performed to determine the patient's response to bronchodilating asthma medication. This is done by administering a bronchodilator to the patient after he or she has performed a spirometric test (Pre-Test). Approximately 10 to 20 minutes after the medication a second spirometric test is performed, pre-test and post-test results are compared. This test can only be added to previous tests on the same day.

The bronchodilator test always consists of two measurements: one before and one after medication.

DANGER
PATIENT HAZARD — Bronchial provocation tests can be dangerous for patients! A primary condition for safe provocation test procedures is a trained and experienced physician.

Physicians must be familiar with the appropriate precautions, guidelines, hazards, and contraindications as defined in the medication documentation and in the standards, to determine when to stop a test as defined in the medication documentation and in the standards.

Observe the contraindications for the medication used, such as:

- General clinical instability of the patient.
- Severely reduced lung function.
- Treatment with beta blockers.
- Hyperresponsiveness.
- Pregnancy.

A physician must be present while bronchial provocation tests are being performed. The patient should never be left unattended during the tests.

The following should be available throughout the bronchial provocation tests:

- A medical specialist capable of treating acute bronchospams.
- Appropriate medication and resuscitation equipment (defibrillator, cardiac pacemaker).

Conducting a Bronchodilator Test

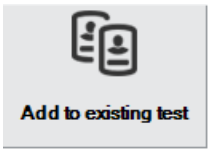
1. Click *Start Pre-/Add Post-Test: <Test_Name>* / *Add to existing test* to start the measurement.

Note

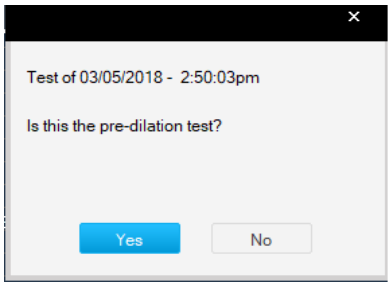
Add to existing test is applicable for tests conducted on the same day.



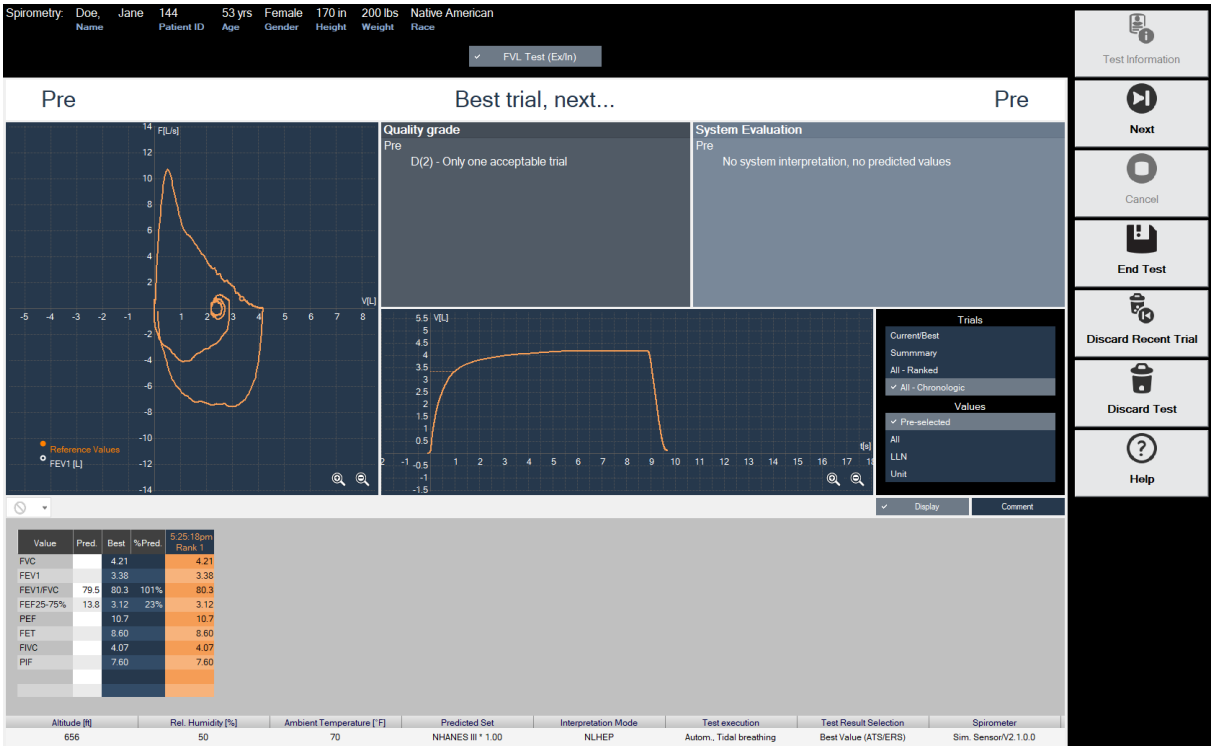




If the patient had a spirogram done the same day, the following message displays..

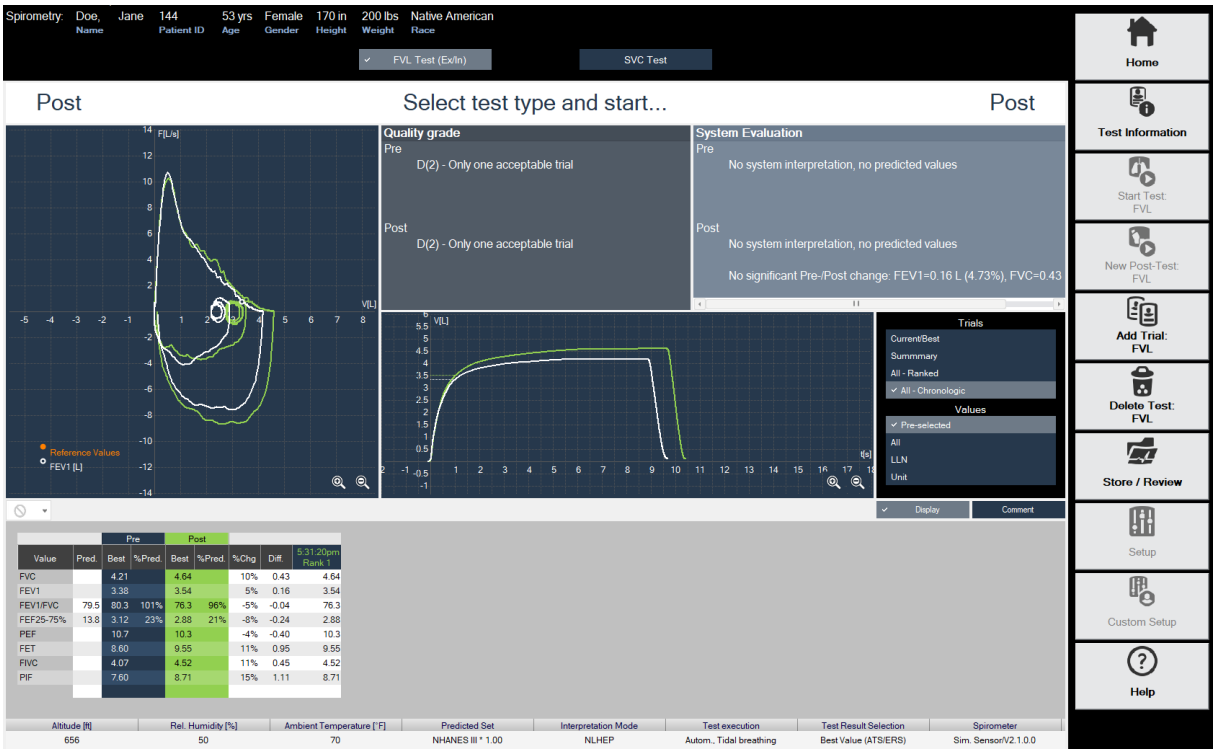


2. Select *Yes* to proceed conducting a pre-spirometry test as normal flow-volume measurement. See "Conducting a Spirometry Test" on page 8-12.



3. Select *End Test* and administer a bronchodilator to the patient and wait for approximately 10 or 20 minutes.

4. Select *Add Post-Test* to conduct a post-spirometry test.



Value	Pred.	Pre Best	Pre %Pred.	Post Best	Post %Pred.	%Chg	Diff.	5:31:20pm Rank 1
FVC		4.21		4.64		10%	0.43	4.64
FEV1		3.38		3.54		5%	0.16	3.54
FEV1/FVC	79.5	80.3	101%	76.3	96%	-5%	-0.04	76.3
FEF25-75%	13.8	3.12	23%	2.88	21%	-8%	-0.24	2.88
PEF		10.7		10.3		-4%	-0.40	10.3
FET		8.60		9.55		11%	0.95	9.55
FIVC		4.07		4.52		11%	0.45	4.52
PIF		7.60		8.71		15%	1.11	8.71

Altitude [ft]	Rel. Humidity [%]	Ambient Temperature [°F]	Predicted Set	Interpretation Mode	Test execution	Test Result Selection	Spirometer
656	50	70	NHANES III * 1.00	NLHEP	Autom., Tidal breathing	Best Value (ATS/ERS)	Sim. Sensor/V2.1.0.0

5. Select *End Test*.
6. Select *Store/Review* to compare a pre-dilation test with the current test.

Delete Test

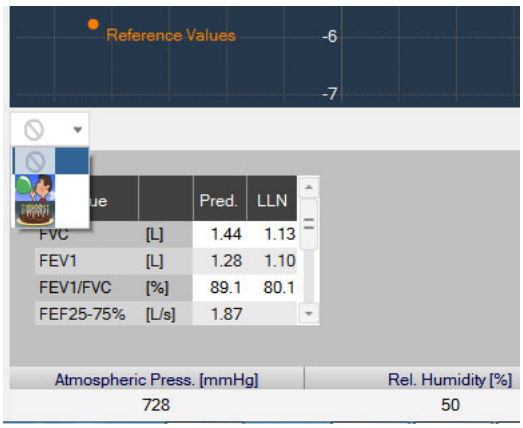
1. Click *Delete Test: <Test Name>*. A confirmation message displays.
2. Click *Yes*.

Children's Animation Program

An animation program for children is available for FVC and FVL tests.

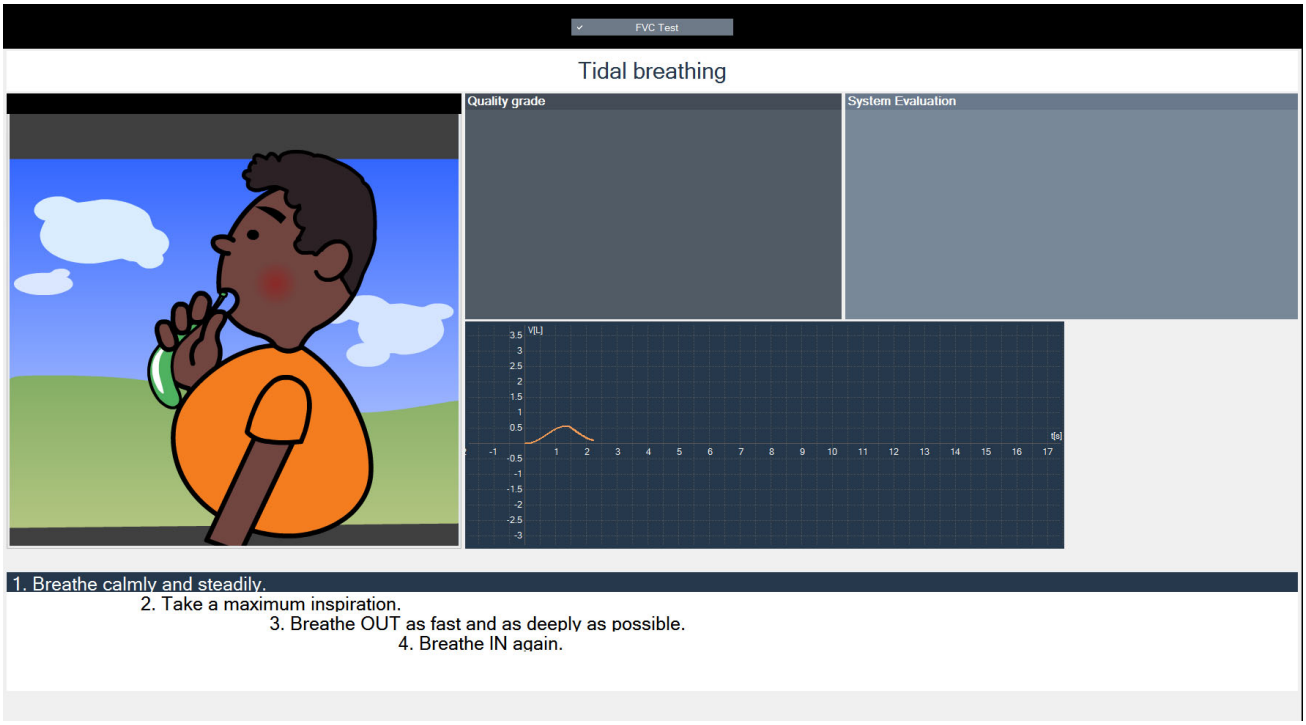
Disable the manual test stop and work with the automatic test stop option when running the animation program.

1. Click the animation icon at the bottom left of the Test Screen.
2. Select the graphic of the ballon, or the candles.

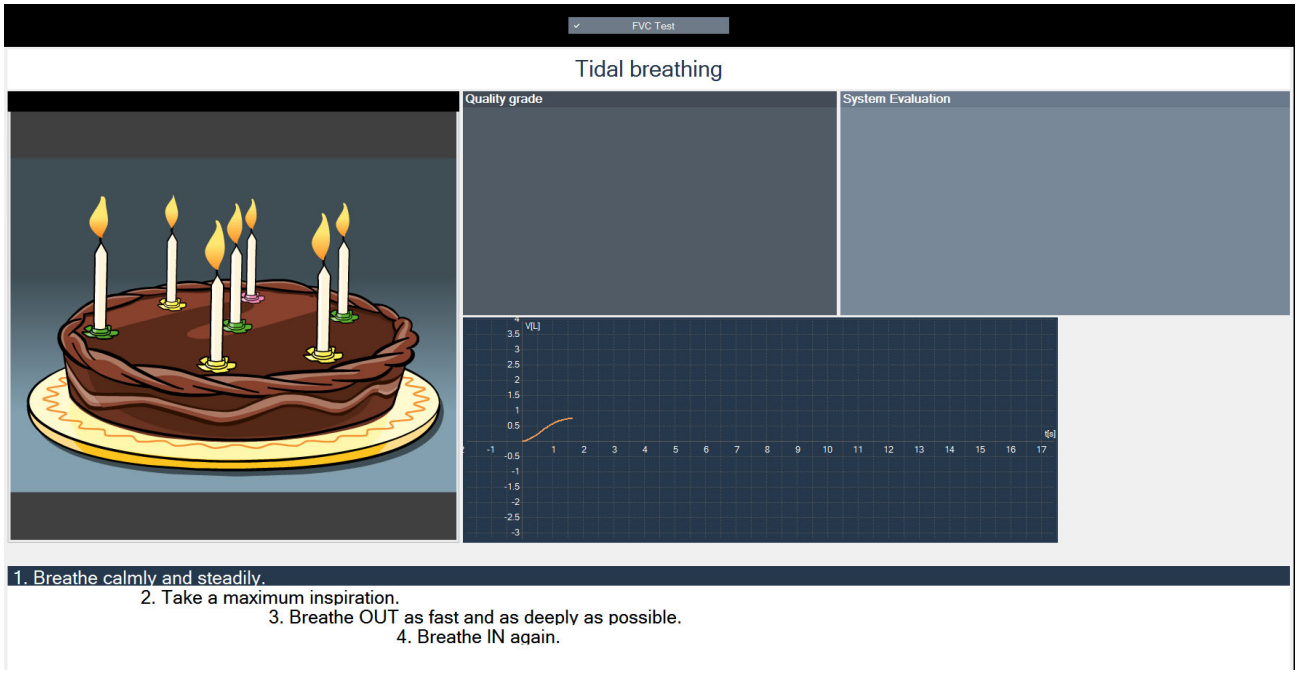




The following figure displays the balloon animation.



The following figure displays the candle animation.



To conduct the spirometry test for the pediatric patient, see "Conducting a Spirometry Test" on page 8-12.

Post Test Review

Test Summary

The *Modify...* buttons let you to edit or complete the data.

Modifying the patient data will lead to reanalysis of the test.

In the Patient Information window, you can only enter or correct data that does not affect the calculation of reference values.

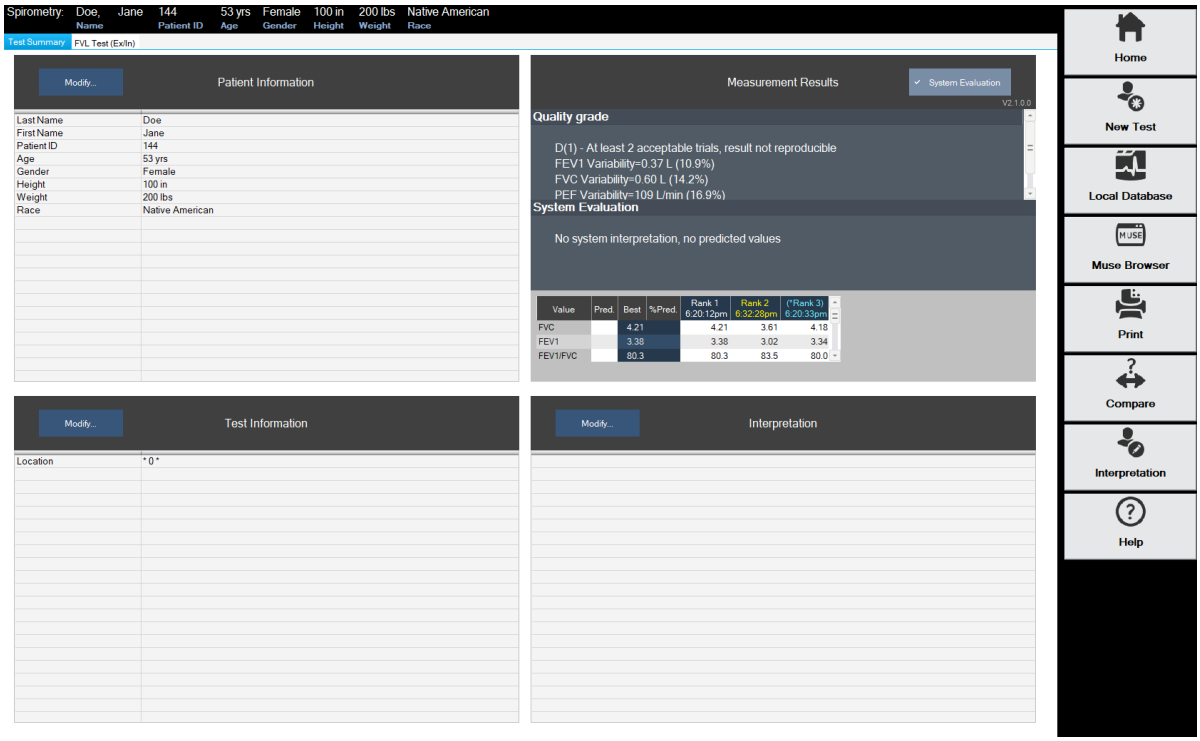
The Test Information is not assigned to the patient, but to the test data.

Click *FVC Measure* to display the acquisition screen with the corresponding flow-volume loop and the measuring values. The status line indicates the ambient conditions set at the time of the measurement.

Store / Review

The Store/Review screen displays the following:

- Patient Information, you can modify the patient information by selecting *Modify*, but you will need to perform the test again.
- Measurement Results, for more information see "Quality Messages/ Grades" on page 8-26.
- Test Information, for more information see "Entering Patient Information" on page 8-9.
- Interpretation, for more information see "Interpretation Screen".



Interpretation Screen

At the end of the test the system evaluation is automatically entered in the interpretation window. Click *Interpretation* or *Modify...* to open the window. In the left part of the window you see a number of folders with standard interpretation text. The system supports the creation of an interpretation by providing standard text which can be copied to the Interpretation area. In the Interpretation area, you can edit the text as needed. See "Editing the Interpretation Library" on page 12-23 for information on editing the standard text.

Quality Messages/Grades

FVC/FVL Quality Messages

A test ends and end-of-test criterion is met when the volume change during the last 2 seconds is <45 ml, or an inspiratory volume >150 ml is detected.

The following messages may display.

Message	Recommended Action
Don't hesitate…	The patient must exhale all air at once and not exhale in short bursts.
Blast out faster…	The patient must exhale more explosively and as firmly and quickly as possible.
Blow out longer…	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs.
Abrupt end of trial!	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs.
Started too early! Wait for start indication!	Instruct the patient to wait until the baseline setting is finished and the device signals that the trial can start ('Start manoeuver …')
Cough detected...	Instruct the patient to avoid coughing during the first second. Repeat the trial.
No manoeuver detected	Instruct the patient to perform the manoeuver according to its definition.
Best trial, next… 2nd best trial, next… 3rd best trial, next… Good trial, next...	The trial is accepted.
Test completed	The test is complete. Quality Grade A or B is achieved. An adequate number of accepted trials is available.

FVC/FVL Quality Grades:

Rating	Criteria
A	At least 3 acceptable trials (for age 6 and under: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 100 mL (80 mL if FVC < 1.0 l) (for age 6 and under: 80 mL or 8% of FVC or FEV1, respectively, whichever is greater)
B	At least 3 acceptable trials (for age 6 and under: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 150 mL (100 mL if FVC < 1.0 l) (for age 6 and under: 100 mL or 10% of FVC or FEV1, respectively, whichever is greater)
C	At least 2 acceptable trials AND the difference between the best two FEV1 and FVC values is equal to or less than 200 mL (150 mL if FVC < 1.0 l) (for age 6 and under: 150 mL or 15% of FVC or FEV1, respectively, whichever is greater)
D(1)	At least 2 acceptable trials but the results are not reproducible according to 'C'. Quality message: "Result not reproducible"
D(2)	Only one acceptable trial. Quality message: "Only one acceptable trial"
F	No acceptable trial available

SVC Quality Messages:

Message	Recommended Action
No Steady-Tidal breathing detected	Instruct patient to breathe quietly and steadily.
Manoeuver incomplete (no ERV)	Perform SVC test according to ERS/ATS recommendation.
Manoeuver incomplete (no IRV)	Perform SVC test according to ERS/ATS recommendation.
Started too early! Wait for start indication!	Instruct the patient to wait until the baseline setting is finished and the device signals that the trial can start.
Best trial, next… 2nd best trial, next… 3rd best trial, next… Good trial, next...	The trial is accepted.
Test completed	The test is complete. Quality Grade A is achieved. An adequate number of accepted trials is available.

SVC Quality Grades:

Rating	Criteria
A	At least 3 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL.
B	At least 2 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL.
D(1)	At least 2 acceptable trials but the results are not reproducible according to 'B'.
D(2)	Only one acceptable trial.
F	No acceptable trial available

Print the Report

Click the *Print* button to print the report. The print for example, window opens where you can temporarily adjust the settings for the printout. See "Miscellaneous Tab" on page 12-26 for details on changing the for example, permanently.

1. Select the documents to be included in the report
2. Select the number of copies to print.
3. Select a format for the Configured Report (click *Modify...* to display the Report Editor).
4. Select the printer.
5. Click *Print*.

Comparing the Test Results

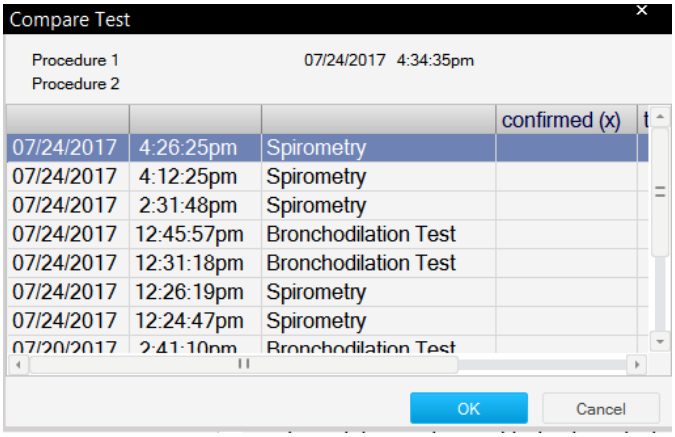
The comparison screen displays the test results of two trials side-by-side. The result includes quality grade, system evaluation, test information, and their interpretation.

1. Select *Compare*.

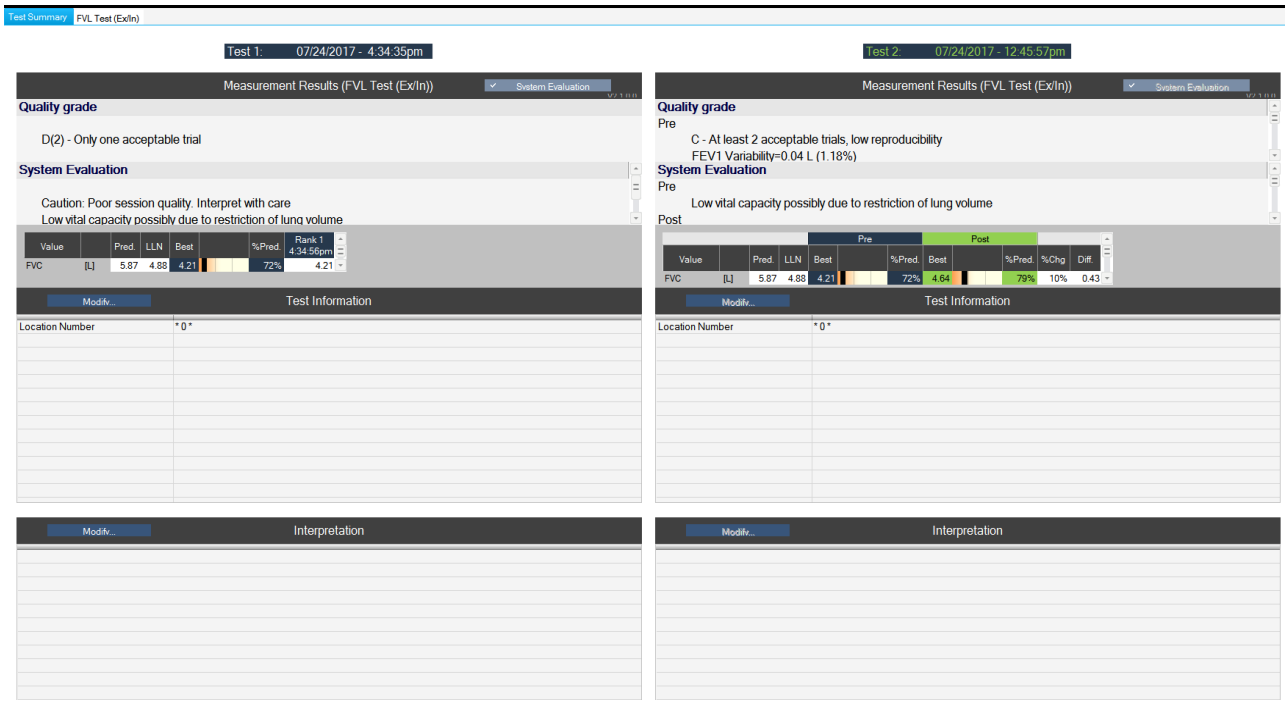


The *Compare Test* window opens.

2. Select the required test to be compared.

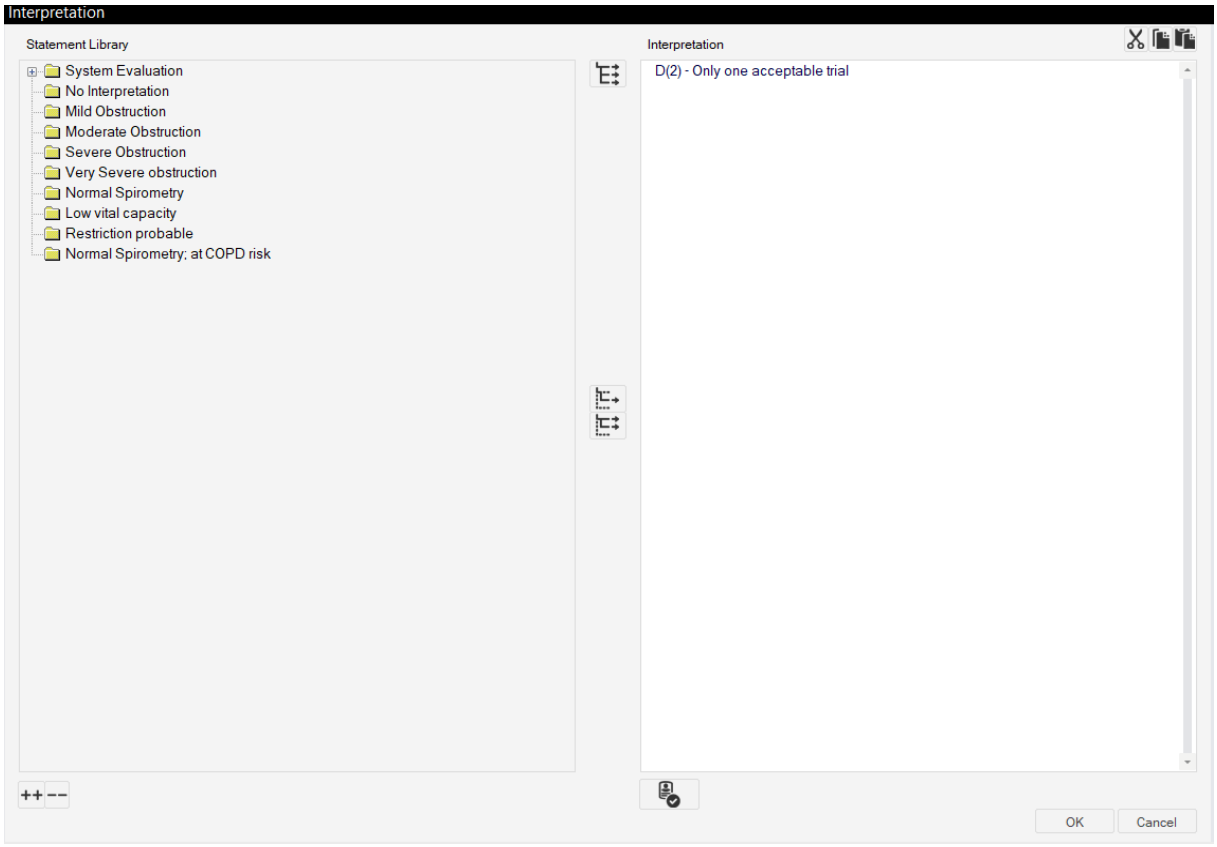


The quality grade, system evulation, test information, and interpretation details display.



3. Select *Modify* to edit or delete any of the test information details.
4. Select *Modify* to edit the interpretation details.

The *Interpretation* window displays with the statement library.



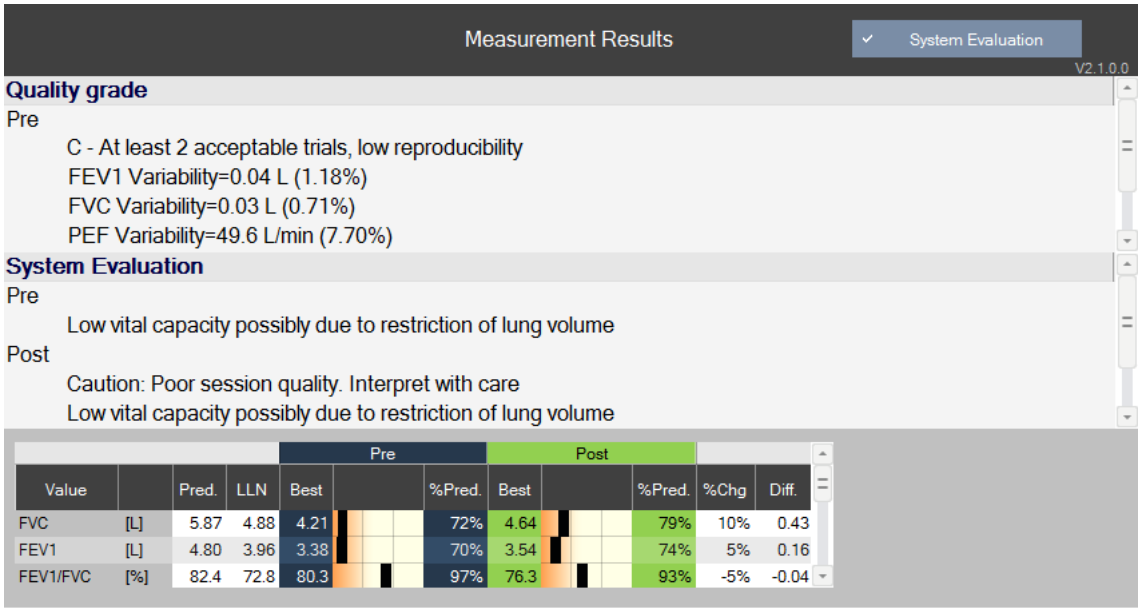
Use the following buttons.

Icon	Description
	Copy the branch.
	Copy the line.
	Copy the line and chapter.
	Show or hide subfolders

5. Select *OK* to view the comparison results.

System Evaluation

In assessing the system interpretation, it is important to consider the quality grade of the test. Quality grades A to C indicate a reliable result. A Quality grade of D or F indicates inadequate test quality. The result must then be interpreted with caution.



Changing Trial Status

The trial status can be changed by moving the desired trial to the required grade/rank. The quality grade also changes and an asterisk displays.

The following table describes the trial change options:

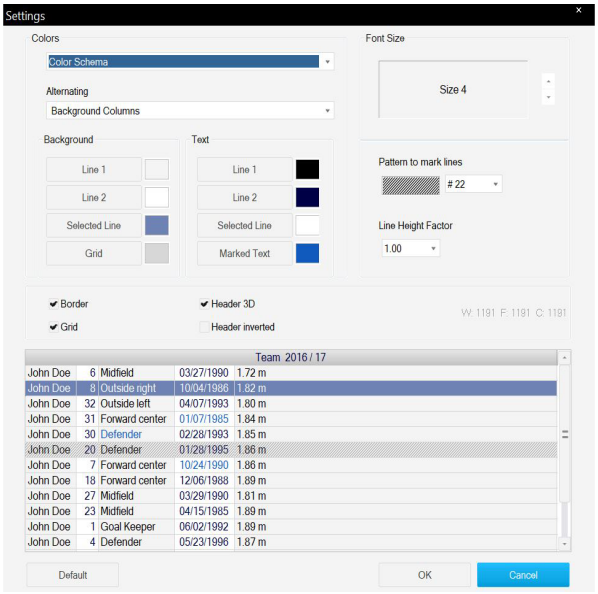
Options	Description
Refuse Trial	You can refuse a trial.
Set to best trial	Displays the selected trial as grade/rank 1.
Reset trial	Any changes applied are reset to their original state for the selected trial.
All trials to original state	Any changes applied are reset to their original state for all the trials.
Delete trial	Deletes the trial option selected.

Changing Display Settings

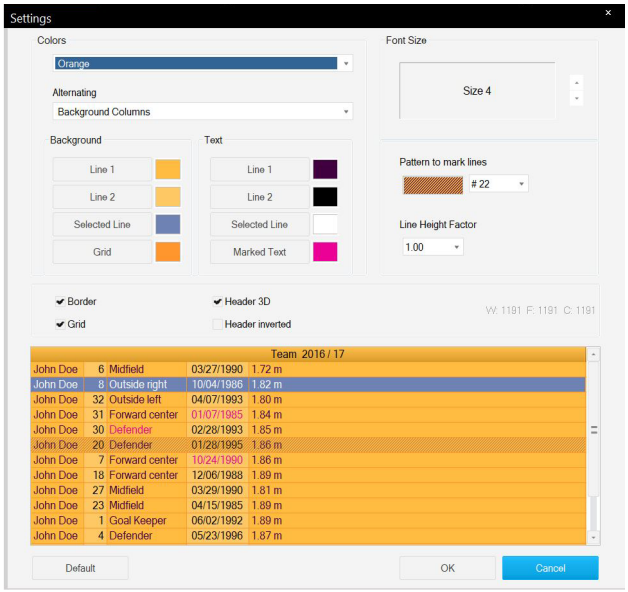
You can edit the display settings on the following screens:

- Instruction to the patient
- Trial data
- Quality grade
- System evaluation

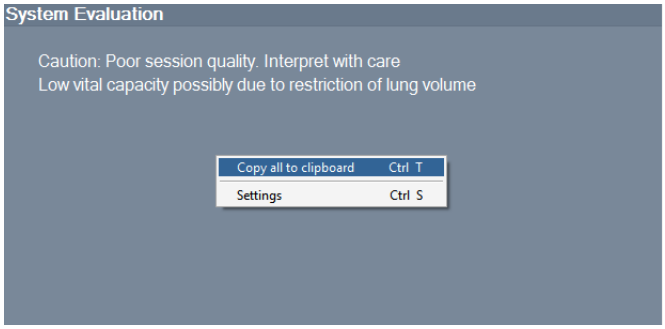
1. Right-click on the relevant screen and select *Settings*. The *Settings* window opens.



2. Customize the settings as required and select *OK*. The change settings display.



Right-click and select *Copy all to clipboard* to copy the contents of the quality grade/system evaluation/ambient conditions.



Parameters Definition

FIVC	Forced Vital Capacity (inspiratory)	forced inspiratory vital capacity
FEV1	Forced Expiratory Volume	(1 s) forced expiratory volume after 1 second
FEV6	Forced Expiratory Volume	(6 s) forced expiratory volume after 6 seconds
FEV1/FVC		ratio of FEV1 to FVC
FEV1/VCmax		ratio of FEV1 to VCmax
FEV1/FEV6		ratio of FEV1 to FEV6
FEF 75 (MEF 25)	Mid-Expiratory Flow (25%)	flow at 75% of expiratory vital capacity
FEF 50 (MEF 50)	Mid-Expiratory Flow (50%)	flow at 50% of expiratory vital capacity
FEF 25 (MEF 75)	Mid-Expiratory Flow (75%)	flow at 25% of expiratory vital capacity
MEF 25-75	Mid-Expiratory Flow (25%-75%)	flow at 25% to 75% of expiratory vital capacity
PEF	Peak Expiratory Flow	peak expiratory flow
PIF	Peak Inspiratory Flow	peak inspiratory flow
FET	Forced Experation Time	duration of expiratory phase
BEV	Back Extrapolated Volume	back extrapolated volume
VT	Tidal Volume	tidal volume at rest
ERV	Expiratory Reserve Volume	expiratory reserve volume
IRV	Inspiratory Reserve Volume	inspiratory reserve volume
VC or VCmax	Maximum Vital Capacity	maximum vital capacity of a slow spirometric test
VCex	Expiratory Vital Capacity	expiratory vital capacity of a slow spirometric test
VCin	Inspiratory Vital Capacity	inspiratory vital capacity of a slow spirometric test
IC	Inspiratory Capacity	inspiratory capacity (VT + IRV)
MVV	Maximum Voluntary Ventilation	maximum ventilation volume per minute
% Chg (PRE/ POST %)		percentage deviation of the pre and post medication values (bronchodilation test)

Troubleshooting

Problem: If you see the error message “Self-test failed” on the display.

Solution: Quit the program and restart. If you receive the same message again, contact your GE Technical Support.

Problem: If you see the error message “The spirette is not correctly positioned.” on the display.

Solution: Ensure that the triangle on the spirometer is lined up with the triangle on the spirette.

Problem: Calibration check outside of ±3.5%.

Solution:
- Insert the spirette.
- Use the ndd calibration adapter.
- Check the connections.
- Choose the correct syringe volume via **Configuration > Test > Cal-Check**.

Note

For additional support, contact local GE Healthcare representative.

9 File Management

For your notes

Overview

All patient records are saved to the local database. The patient records can be:

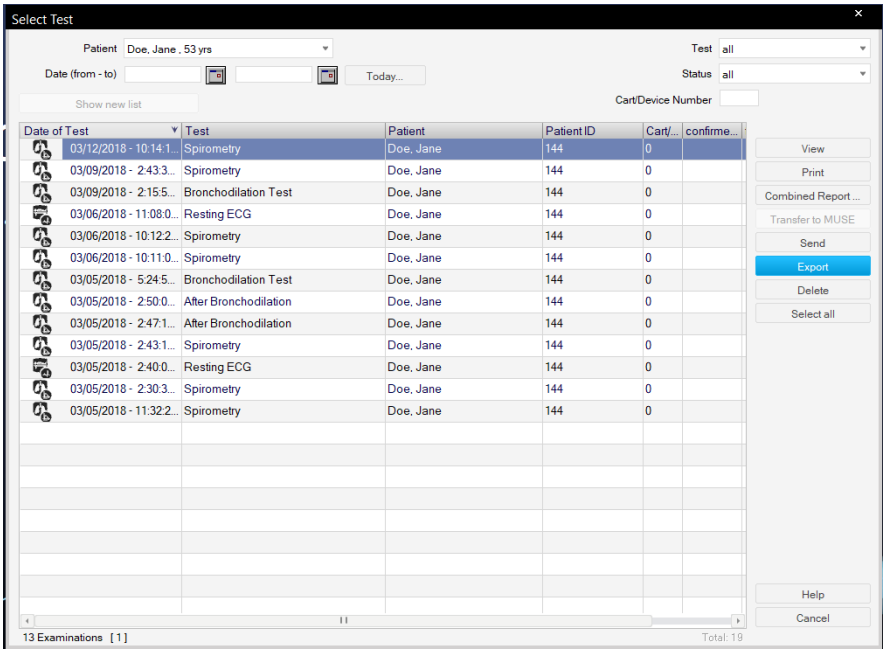
- Viewed, edited, deleted, and printed.
- Export to another storage medium.
- Transferred to the MUSE database system or deleted.

Click *Local Database* to open the window with the names of all stored patients.

In this window, you can:

- click Test to view all tests.
- select a patient and then click Test to view only this patient's tests.

Selecting Patient Records



1. Type *all* in the *Patient* list box to see all stored patient records and not just those of the selected patient.

2. To reduce the number of displayed patient records
   - Enter a *Cart/Device Number* to view only those patient records acquired with that cart/device.
   - Enter a time period at *Date (from - to)* to view only those patient

records acquired in that period.

- Click *Insert today's date* to view only today's patient records.
- Select a test type from the *Test* list.
- Select a test status from the *Status* list.

3. Click *Show new list* to update the list according to your selection.
4. Click a patient record.

Note

Patient records marked with an asterisk * are stored on an external medium.

You can select multiple patient records, holding the **Shift**.

Right-click and select Copy all to clipboard to select all displayed patient records.

In a network environment, do not review a patient's test at more than one workstation at a time.

Viewing, Editing, Printing Patient Records

Click *View*. The *Test Summary* opens.

You can edit the information. Changes are saved automatically to the local database when you exit the screen. To print the displayed patient record, click the *Print* button.

Note

You can also display a patient record by double-clicking.

When working in a network environment, it is not possible to view the same patient record at multiple workstations.

When selecting a patient record stored on an external medium, the system asks if you want to view the record only (in that case it remains on the external medium) or if you want to restore it to your PC.

Patient records transferred to the MUSE system database can be viewed and printed with the MUSE Browser.

When you have selected the option *Delete local test data after transfer to MUSE* on the *MUSE* tab (see section "MUSE Tab" on page 12-44), all test data will be automatically deleted from the local database. Only the patient demographics remain stored.

Printing a Combined Report

For the selected patient, you can generate and print a Combined Report covering multiple records.

1. Select the patient.
2. Select a record (or select multiple records, holding the **Shift** key).

3. Click *Combined Report*.

   The Combined Report is displayed.

The Combined Report can be edited and printed, but it cannot be saved.

Viewing and Printing Patient Records from the MUSE System

1. Click *MUSE Browser* on the initial screen.
2. Enter the MUSE password, if prompted. The MUSE web page will appear.
3. Select *Display with Frame* or *Display without Frame*.
4. Submit query or identify the patient record to be retrieved by patient ID or name.
5. Display the individual documents of the patient record.
6. Print reports using the Acrobat Reader printer tools on screen (tool bar directly above the report page).

Use the Internet Explorer printer tools (toolbar at the top of the screen).

Archiving, Exporting, Deleting Patient Records

Select the patient record(s).

- To select a series of consecutive records, hold down the Shift key and click the first and last file name of the series.
- To select individual records, hold down the Ctrl key and click on each single record you wish to select.
- To select all displayed patient records, click Select all.

Save to Archive

To save to CD, the CD must be formatted. Use SD cards only to transfer data from MAC ECG systems.

To save the selected patient records to a CD, click *Save to Archive*.

Transfer to MUSE

To transfer the selected patient records to a MUSE system, click *Transfer to MUSE*.

Note

This button is enabled only if the data transfer to the MUSE system has been enabled on the *MUSE* tab.

Data sent to the MUSE system can be edited only when the program is configured accordingly. (see "MUSE Tab" on page 12-44).

Data sent to the MUSE system can be viewed and printed with the MUSE Browser. Select the Landscape format before each printout.

Send

Click the *Send* button to send the selected patient records via modem or save them to a storage medium.

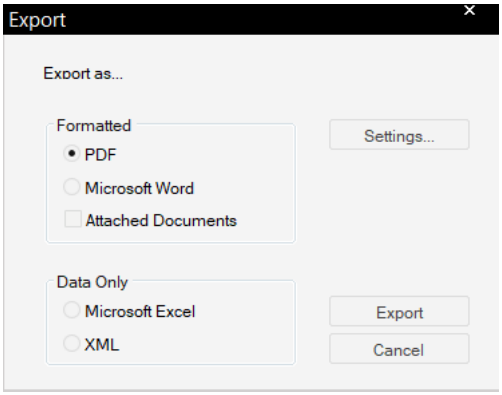
To send records via modem

- Click *Transmission via modem*.
- Enter the telephone number, name and password of the workstation at the receiving end.
- Click *OK* to clear the window.

To save records to a storage medium

- Click *Save procedure to storage medium*.
- Click *OK*.

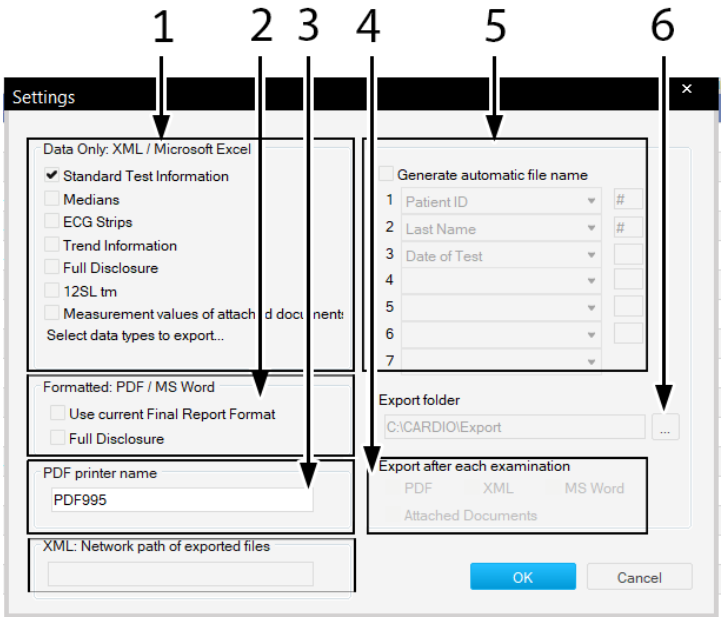
Exporting a Patient Record



1. Click *Export*.
2. Select the export format.
3. Optional: Configure the export settings.
4. Click *Export* to export the data.

For the *PDF* format, select the documents to print in the *Print* window. If you do not use the PDF995 *PDF printer driver* to export data in the PDF format, you must set the export folder in the corresponding PDF writer application.

Settings



1 Select the data to export as XML/Excel files.

2
- *Use current Final Report Format* - Select check box if you wish to use the settings from the Final Report tab (see "Run the Final Report" on page 12-6 and "Run the Final Report" on page 12-14). Otherwise the setup screen for configuration of the final report will appear.
- *Full Disclosure* - Select check box if you wish to use the settings from the Full disclosure tab.

3 Enter the printer driver for PDF files.

4 Select check box if you wish to automatically export each test after completion as a PDF, XML or Word file and with the name (5), and whether the attached documents are to be included in the export.

After you select the *Attached Documents* and *XML* fields or *PDF* and *XML* fields, the *XML Network part of exported files* field is enabled. The entry in this field is used in the "XML tag <Export><FileName>" to define the network path of the exported PDF files for access from external computer systems.

5 Select the patient and/or test information to be included in the file name that the system will generate automatically:
- test type
- date
- patient's last name
- patient's first name
- patient's date of birth
- patient ID
- patient record no.
- export date

6 Select the target folder for the data export.

Note

If you do not use the PDF995 *PDF printer driver* to export data in the PDF format, you must set the export folder in the corresponding PDF writer application.

Working Temporarily with the Local Database

Note

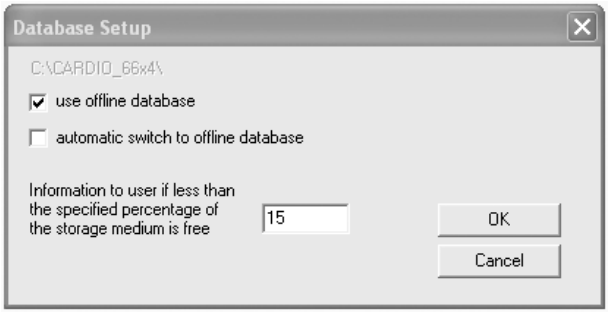
This feature is not available if any of the following options is enabled:

- DICOM option (DICM).
- EMR option (XEMR).
- Request MUSE data.
- Floating License.

To work with the offline database, copy the patient list, without any examinations, to the local database. This can be done manually or automatically.

Manual

1. Connect the PC to the data network.
2. Click *System Configuration* to display the system configuration menu.
3. Click *Database...*
4. In the *Database Setup* window select *use offline database*.



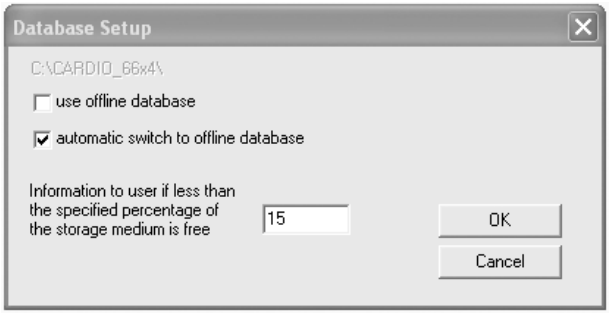
The patient list without the corresponding examinations will be copied to the local database.

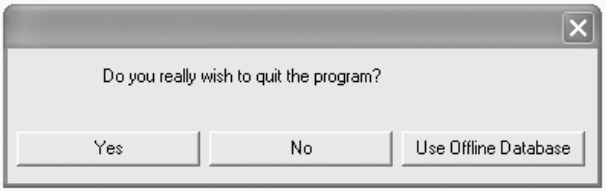
You can disconnect the PC from the data network and continue working with the local database.

When you have finished working with the local database, reconnect the PC to the network and deselect the *use offline database* check box: new tests as well as new patients for whom tests exist will be copied to the database on the server.

Automatic

If you select the *automatic switch to offline database* check box in the *Database Setup* window, an additional button will be displayed when you shut down the program: *Use Offline Database*.





When you end the program with this button, the patient list will be copied to the local database.

When you have finished working with the local database, exit the program, reconnect the PC to the network and start the program. New tests as well as new patients for whom tests exist will be copied to the database on the server.

10 Operation with Administrative Tools

For your notes

Overview

The program can be used in combination with the following administrative tools:

- Medical reimbursement program.
- Hospital information system (HIS).
- EMR system (electronic medical records).

Description

The CardioSoft program supports communication with administrative tools via the following interfaces:

- GDT (German medical device data standard).
- BDT (German medical data standard)
- HL7 (requires XEMR option).

Note
Refer to the separate descriptions supplied.

If the program is used in conjunction with an administrative tool, the patient file is always managed in the administrative tool while the test data are managed in the CardioSoft program. In this case, you will also select the patient in the administrative tool and enter height and weight.

After selecting the patient, choose the test type. This will automatically transfer you to CardioSoft which you operate as usual. If you wish to select another patient, you will have to exit the examination program and choose the patient in the administrative tool.

After ending the test and terminating the examination program, the most important data, but no curves, will be transferred to the administrative tool.

Perform the following steps:

1. Start the administrative tool.

2. Select the patient.

3. Display patient's medical record.

4. Select an examination (start of CardioSoft).

5. Acquire a new test (ECG, spirogram, etc.).

6. End the examination program.

7. Transfer test data to the administrative tool.

When running CardioSoft in conjunction with an administrative tool, the functions *selecting another patient, admitting a new patient* are not available.

The patient is admitted to the administrative tool with last name, first name, patient ID, date of birth, height and weight.

Note

GE Healthcare is not in position to guarantee full compatibility of the administrative tool with CardioSoft in all situations.

11 DICOM and DCP Interfaces

For your notes

About DICOM

Digital Imaging and Communications in Medicine (DICOM) is an open data exchange standard for medical information.

DICOM standardizes both the file format for data storage as well as the communications protocol for the exchange of these data.

A valid DICOM option code activates the DICOM interface and the *DICOM* tab.

For *DICOM* tab configuration, refer to your IT/Service staff (see Field Service Manual).

About DCP

The DCAR Communication Protocol (DCP) is an interface used by the Cardiac Testing System to send and receive data via DCP protocol, if configured. It provides a service to request and receive data from clinical systems implementing a DCP server. It can then send data packages to the DCP Server with the results of tests.

DCP Port Configure

Configure the port in connectivity server tab of server computer and then configure the same port in the client computer to establish DCP connection from the client computer.

Do the steps as follow to establish DCP connection:

1. Open server computer
2. Click *Connectivity Server* tab
3. Enter the DCP server details such as *Friendly Name*, *IP Address*, *Copy Location*, and *Port number* (for example, 9240 or 9280)
4. Click *OK*
5. Open client computer
6. Click *DCP* tab
7. Enter *Server Address* with same port as in server computer (for example, http://X.X.X.X:9240/SendTest)
8. Click *Test Device Connection*
9. Click *OK*.

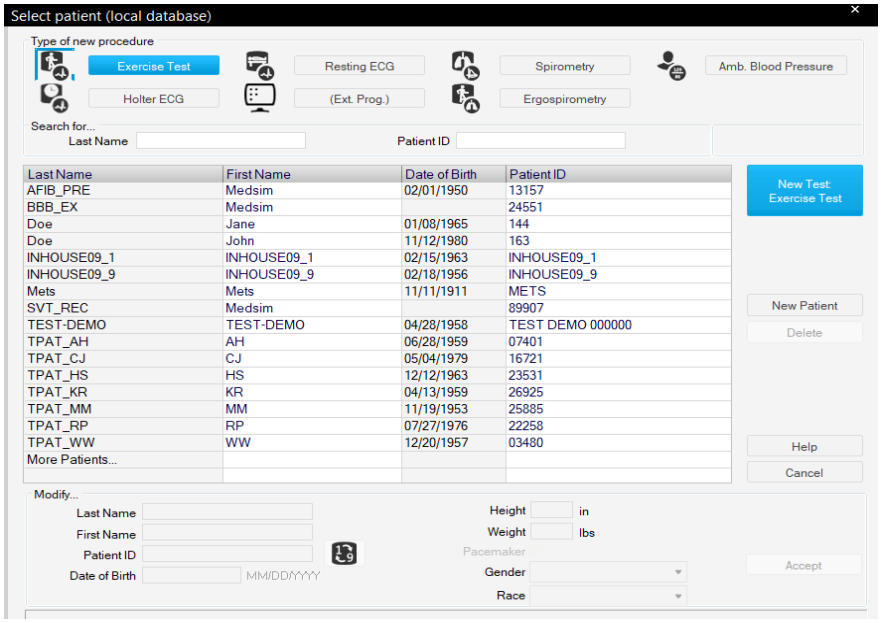
DICOM /DCP Functions

DICOM/ DCP enables:

- Performing procedures on the basis of the order list (scheduled examinations).
- Performing procedures without the order list.
- Sending procedure data to an image archiving system (using the DICOM standard) or a Hospital Information System (HIS) or Electronic Medical Record (EMR) system via the DCP protocol.

Performing Procedures with the Order List

1. Click *New Test*.
2. Select the patient and click *Order List*.



An order list query is automatically sent via the network. These are the default search criteria:

when DICOM is configured

- orders for the selected patient
- orders for the present day (today)
- orders assigned to this workstation

when DCP is configured

- Orders for the selected patient
- Order search by Patient Id/ Last name
- Orders for the specified location

Note

It is also possible to view the order list without selecting a patient first.

3. If required, you can changed these default settings. Then click Find to start the query..
4. Select the order from the list. More details can be found below the order list..
5. Click *Start Procedure.*

The procedure with the patient data of the selected order will start. For exercise stress tests, a test protocol assigned to the order will automatically be selected (see Field Service Manual).

If present, the following data will be saved with the test:

- Order number (configurable source, see Field Service Manual).
- Name of the requesting physician.
- Name of the performing physician.

6. Perform the examination.
7. At the end of the examination you will be asked whether the test is a valid or an invalid test. If invalid, you must state a reason.
8. Confirm your entries.

Once the test has been successfully terminated, or after it has been analyzed, the data will be sent to the archiving system.

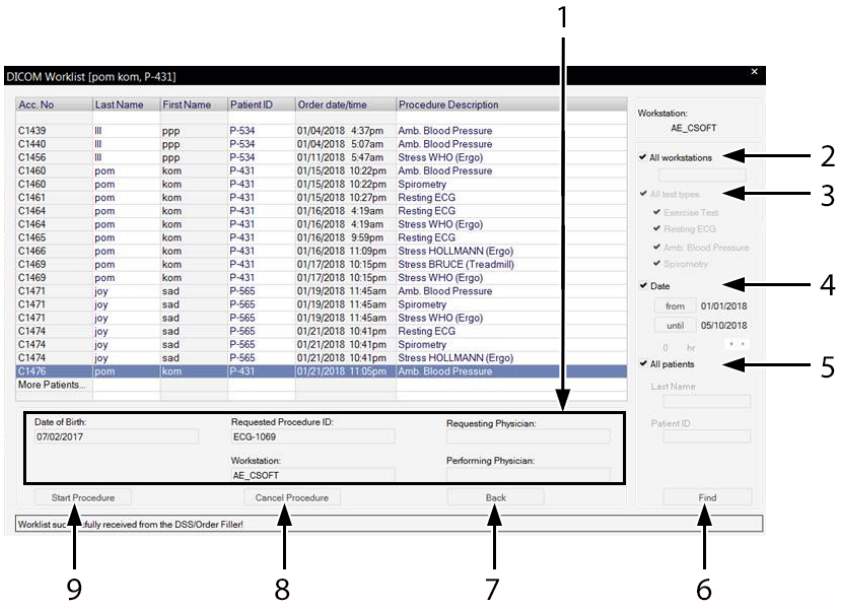
Depending on the DICOM configuration, only the ECG waveforms (for exercise stress tests only) or the ECG waveforms and the test report (as configured for the printout) will be sent to the archive. After a successful transfer the exam is labelled *Transferred (DCM)* in the examination list.

Depending on the DCP configuration,Resting ECG tests, Exercise tests, Spirometry tests, and Ambulatory Blood Pressure tests (as configured for the printout) will be sent to the DCP server. After a successful transfer the exam is labelled *Transferred* in the examination list.

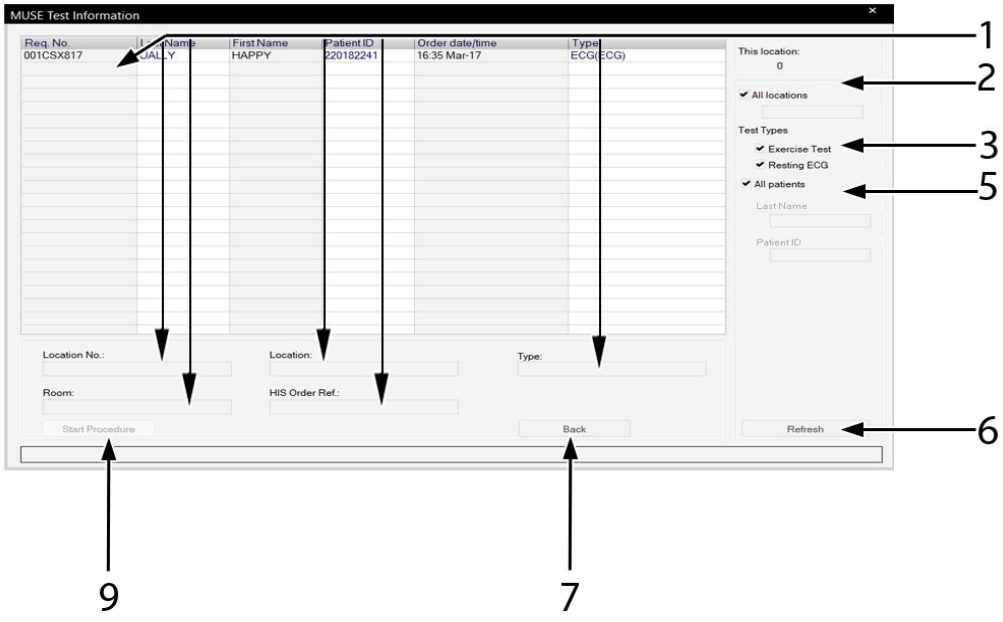
When the data were successfully archived, the exam is labelled *Archived (DCM)* in the examination list. Depending on the configuration, it may not be possible to edit the archived exam.

Elements of the Order List - Explanation

For DICOM Configuration



For DCP Configuration



1 The content of these fields depends on the program configuration.

2 Search criterion for the workstation when DICOM is configured: find orders for a specific workstation or find orders for all workstations.
Search criterion for the locations when DCP is configured: find orders for a specific location or find orders for all locations.

3 Search criterion for test types:
- If DICOM is configured, find orders for Resting ECG, Exercise, Spirometry and/or Ambulatory Blood Pressure tests.
- If DCP is configured, find orders for Resting ECG or Exercise tests

4 Search criterion date: find orders for the selected time period or find orders irrespective of a time period.

5 Search criterion patient name/patient ID: find orders for patients with a given last name or patient ID or find orders for all patients.

6 Refresh/Find orders that match the specified search criteria.

7 Quit the dialog window.

8 Reject the order, stating the reason.

9 Start the procedure of the selected order.

Performing Procedures without the Order List

- Click *New Test*.
- Select a patient or admit a new one.
- Select the test type.
- Start the test.
- The procedure is performed and archived as described in the previous section.

12 System Settings

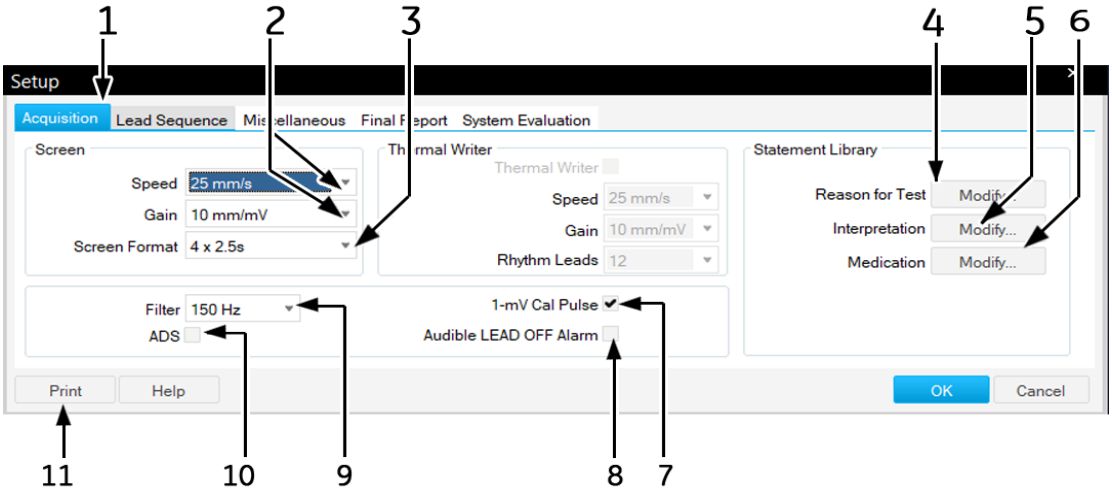
For your notes

Resting ECG Setup

The settings specific to the resting ECG modality can be entered either from the resting ECG acquisition screen where you click *Setup* to display the setup menu, or from the *General* tab of the System Configuration (see "General Tab" on page 12-34).

Acquisition Tab

The *Acquisition* tab with the acquisition settings is already on top.



1	Display the other setup tabs.
2	The speed and gain.
3	The screen format.
4	Edit the *Reason for Test* library (see next page).
5	Edit the *Interpretation* library.
6	Edit the *Medications* library.
7	Select or clear the 1-mV calibration pulse display.
8	Turn on the audible lead off alarm.
9	Filter frequency (ECG).
10	Enable the ADS algorithm (automatic compensation of baseline fluctuation). ADS causes a signal delay of several seconds.
11	Print the resting ECG setup.

Editing the Reason for Test Library

In this window, you can edit the library for the Reason for Test list box. You can enter a maximum of 12 statements.

1. Click *Modify* to display the *Reason for Test* library.

2. Select a blank line.
3. Enter the text.

Editing the Interpretation Library

In this window, you can edit the library of interpretative statements.

1. Click *Modify* to display the *Interpretation* library.
2. Double-click an interpretation statement to edit it.

Editing Medication Groups, Assigning Drug Names

1. Click *Modify* to display the *Medications* library.
2. Click the arrow to open the list.
3. Select the medication group.
4. Click the *Drug Name* box and enter the medication name.

Note
Assigning the correct names to the groups is the responsibility of the physician.

Lead Sequence Tab

Click *Lead Sequence* to open the window.

Lead sequence is the assignment of ECG leads to the writer or screen channels.

You can change the lead sequences according to your needs and save them under the same name or under a new name. You may also create new lead sequences.

Note
The *Standard* and *Cabrera* lead sequences cannot be modified.

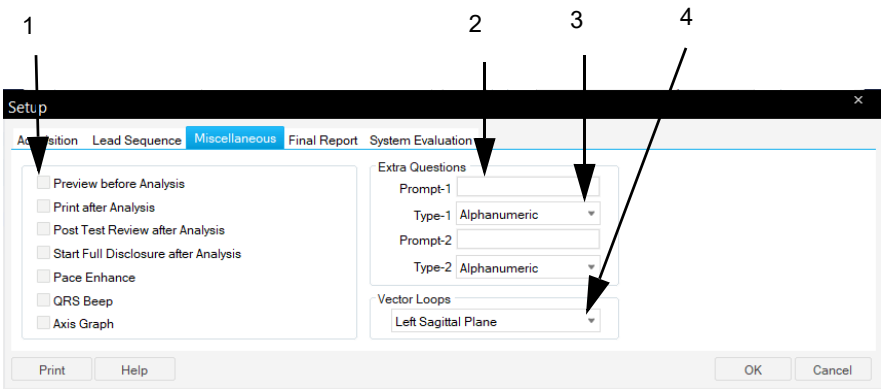
Modifying the Lead Sequence

1. Select the number of monitored leads. These are the leads to be recorded.
2. Select a *Lead Sequence*.
3. Open the list box of the channel where you want to record another lead and select.
4. Enter the lead label.
5. Choose unipolar or bipolar.

6. Choose the first electrode site for Ex1.
7. Select the second electrode site for Ex1 (*bipolar*) (the second site for *unipolar* leads is always CT).
8. If required, change the name of the lead sequence and click *OK* to save.

   If you change any of the selections of an "Ex" lead, the sequence name is given as “?”.

Miscellaneous Tab



1 Select the check box to enable the function:
Preview before Analysis: Full-screen display of the 10-second ECG, analysis only after confirmation.
Print after Analysis: Automatic printout after acquisition of the 10-second ECG.
Post Test Review after Analysis: Automatic display of the test report after acquisition and analysis of the 10-second ECG.
Start Full Disclosure after Analysis: After acquisition of the 10-second ECG, the system starts saving the full disclosure data.
Pace Enhancement: All pacer pulses will be displayed with an amplitude of 0.5 mV.
QRS Beep: The system emits a beep each time it detects a QRS complex.
Axis Graph: An axis graph is shown in *Tabular Summary* and in the *Median Report*.

2 Enter the prompt for Extra Question 1.

3 Select the answer format for prompt 1.

4 Select the sagittal plane (right/left) for vector loop display.

Run the Final Report

Click *Final Reports* for configuration of the report printout.

1. Select the documents to be included in the report:
   - *Configured Report*
   - 10-second ECG (up to 3 different formats, with or without *Interpretation*)
   - *Medians*
   - *Vector Loops*.
2. Select the screen format for the 10-second ECG. You can choose two more formats.
3. Select a report format.
4. Click *Modify* to edit the report or create a new Configured Report.
5. Select the number of copies to print.
6. Select the rhythm leads.
7. Select the printer.
8. Choose the leads if you selected the *Swedish H1* format.
9. Select the check box to print the measurement marks.
10. Select the gain.

Report Editor

The Configured Report Editor allows you to create a maximum of 10 templates (for example, letter to referring physician). Two templates (Reports 1 and 2) are preconfigured and cannot be changed.

Click *Modify* on the *Final Report* tab to display the *Configured Report Editor* window.

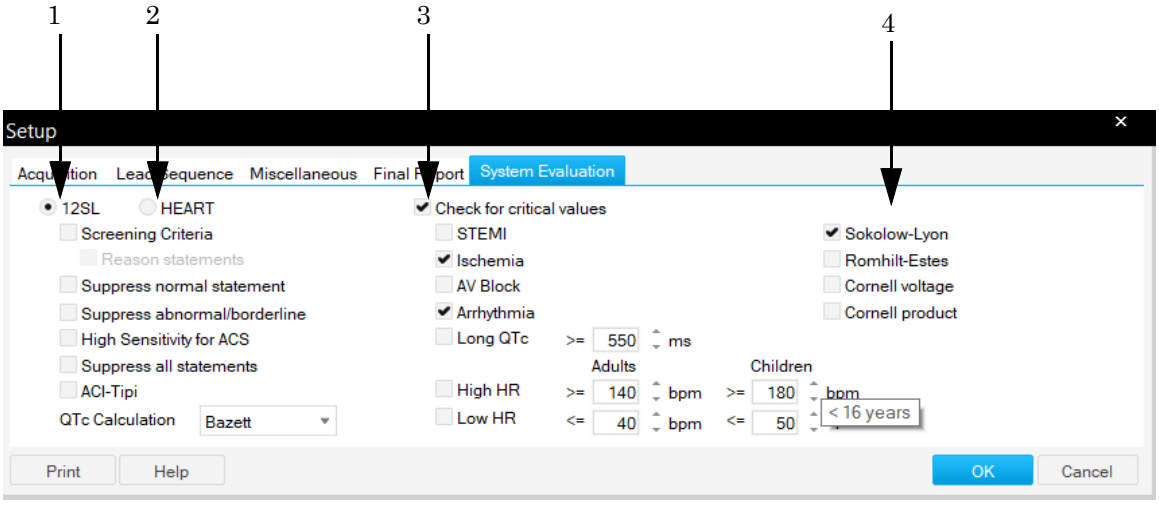
You can enter text and insert report items from a list (for example, patient name, heart rate). At the time the report is printed, the program will replace these report items with the actual data.

1. Click to select and open a report template.
2. Click in the window and type the text.
3. Click *Insert Report Items* to open the list of available data fields and select an item by double-clicking.
4. Highlight the text and select the font.
5. Select the font size.
6. Select the font format: **bold**, *italics* or <u>underlined</u>.

7. Select a color from the color palette *A* and click the colored bar.
8. Select the paragraph format: left flush, right flush, or centered.
9. Click *Logo* to open the logo window.
10. Click *Save* to save the template. To do so, enter the template name first. This name will allow you to select the template later on when configuring the printed report. If edited, Reports 1 and 2 must be saved under a new name.
11. Click *Delete* to delete the template.
12. Close the *Configured Report* window.

System Evaluation Tab

Click *System Evaluation* to configure the test analysis report for 12SL and Heart analysis.



1 12SL analysis program:
Select the check box to display the corresponding statements in the Test Summary (ACI-TIPI (Acute Cardiac Ischemia - Time Insensitive Predictive Instrument) is a mathematically-based decision aid which has been shown to be useful in critical care situations where speed of diagnosis can be crucial).

2 HEART analysis program.

3 Select the critical values for display in the test report.

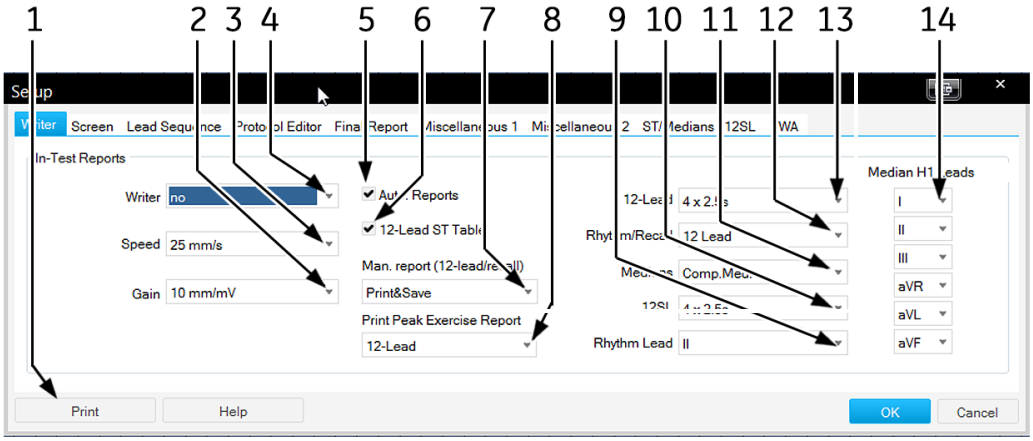
4 Select Sokolow-Lyon, Romhilt-Estes, Cornell voltage, and Cornell product to display the values in the test report.

Exercise Test Setup

The settings specific to the exercise test modality can be entered either from the exercise test pre-acquisition screen where you click *Setup* to display the setup menu, or from the *General* tab of the System Configuration (see "General Tab" on page 12-34).

Writer Tab

The *Writer* tab with the writer settings is already on top.



1 Print the exercise test setup.

2 The writer gain.

3 The writer speed.

4 Select writer for In-Test Reports.

5 Select automatic in-test reports configured in the *Protocol Editor* (see "Protocol Editor Tab" on page 12-12).

6 Select display of the ST Table in the 12-lead reports.

7 Output of manually acquired in-test reports: *Print*, *Print&Save* or *Save*.

8 Peak exercise report type: *none*, *Medians*, *12-Lead* ECG.

9 Rhythm lead for viewing and recording.

10 *12SL* report format.

11 *Medians* report:
- Select the rhythm lead for Linked Medians at I.
- Select the leads for Median H1 at N.

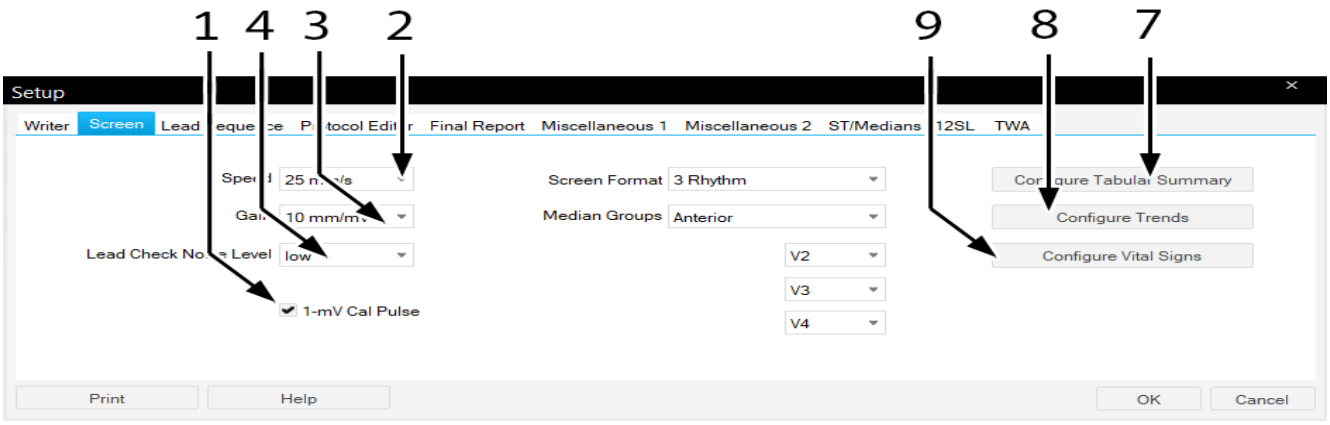
12 *Rhythm/Recall* report format.

13 *2-Lead* report format.

14 *H1* ECG leads.

Screen Tab

Click *Screen* to open the window.



1. Select to display the 1-mV calibration pulse.
2. The speed for the displayed ECGs.
3. The gain for the displayed ECGs.
4. The sensitivity level to noise (noise/signal ratio): low, middle, high (electrodes with a high impedance are shown yellow).
5. Select the ECG format for the screen display.
6. The median group, and the leads for this group.
7. Configure the *Tabular Summary*.
8. Configure the *Trends*.
9. Configure the *Vital Signs* window.

Configuring the Tabular Summary

You can define up to five columns of data in the Tabular Summary in addition to the standard eight.

Select preconfigured data types or create new column headings.

Click *Configure Tabular Summary* on the "Screen Tab" on page 12-9 to display the configuration window.

The highlighted items are selected for display.

1. Click a highlighted item to deselect it.
2. Click a deselected item to select it.
3. To create your own column headings:
   a. Type the new column heading.
   b. Click a heading to select it.

Note

You can enter the values for columns 1 through 5 either directly in the Tabular Summary or use the **comment** key.

Configuring Trends

From the Screen tab, click *Configure Trends* to open the configuration window.

You can choose the parameters for six graphic trends.

1. Select the parameter for the left Y axis.
2. Select the parameter for the right Y axis.
3. Choose the ECG lead for the ST-related graphic trends.

Configuring the Vital Signs

From the Screen tab, click *Configure Vital Signs* to open the configuration window. You can choose the:

- Vital signs to be displayed.
- Order in which they are presented.
- Font size.

1. Click *Add/remove fields* to select the vital signs to display.
2. Right-click a window item to choose a different font size or move the item.

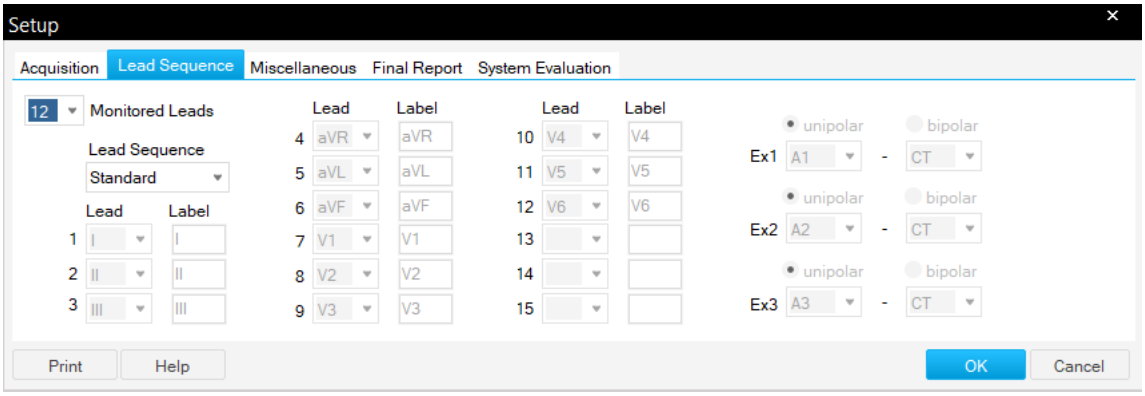
   These are the choices in the menu:

   - move
   - bigger font
   - smaller font
3. Click the appropriate item in the menu to change the font size.
4. Click *Move* to choose another location for the item. A box appears around the selected item.
5. Click in the box and, holding the mouse button down, move it to its new position.

Note

You can define different setups for bicycle ergometers and treadmills.

Lead Sequence Tab



Click *Lead Sequence* to open the window.

Lead sequence is the assignment of ECG leads to the writer or screen channels.

You can change the lead sequences and save them under the same name or under a new name. You may also define different lead sequences for the screen display and the printouts.

Note

The first two lead sequences are fixed and cannot be modified.

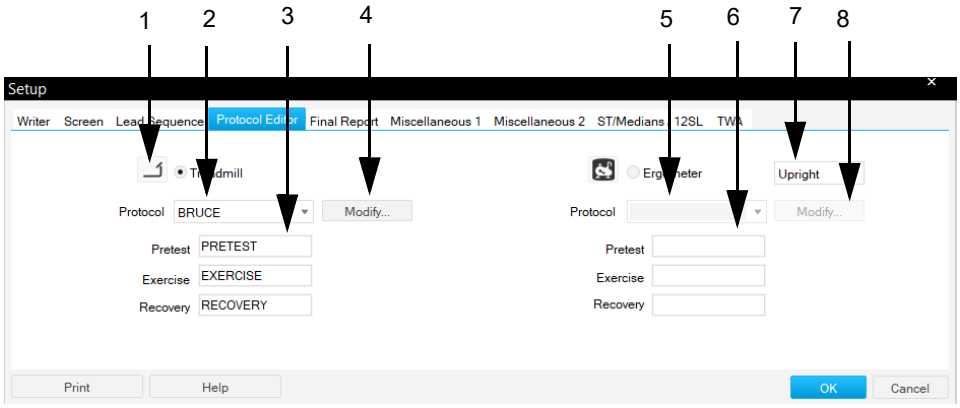
Modifying the Lead Sequence

1. Select the number of monitored leads. These are the leads to be recorded.
2. Select a *Lead Sequence*.
3. Open the list box of the channel where you want to record another lead and select.
4. Enter the lead label.
5. Select the lead for screen display (only possible after definition of the lead sequence).
6. Choose *unipolar* or *bipolar*.
7. Choose the first electrode site for *Ex1*.
8. Select the second electrode site for *Ex1* (*bipolar*) (the second site for *unipolar* leads is always CT).
9. If required, change the name of the lead sequence (step 2) and click *OK* to save.

   If you change any of the selections of an *Ex* lead, the sequence name is given as *???*.

Protocol Editor Tab

Click *Protocol Editor* to open the window.



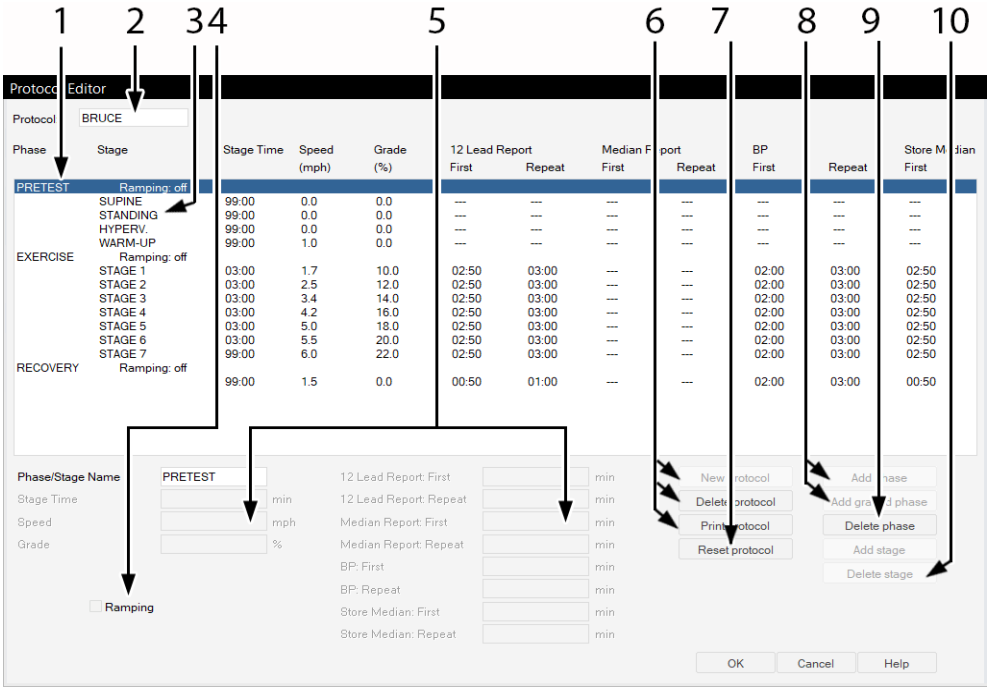
1 Select the treadmill testing device.
2 Select a protocol.
3 Phase names of the protocol.
4 Modify or delete protocols.
5 Select the bicycle ergometer testing device.
6 Select a protocol.
7 Modify or delete protocols
8 Modify or delete protocols.

Selecting the Default Protocol

1. Choose the treadmill or bicycle ergometer exercise testing device.
2. Select the default protocol.
   - You can either select an existing protocol (for example, *BRUCE*) and edit the parameters, or
   - You can create a new protocol from a blank template (for example, *TEST 14*).
3. Click *Modify* F to edit existing protocols or create new ones. This displays the *Protocol Editor* window.

Note
You can select protocols for pharmacological tests (for example, Dobutamine).

Protocol Editor Screen



Note

The *12 lead* and *Median* report formats are selected on the *Writer* tab.

The medians saved with *Store Median* are included in the *Medians* report.

1 Phase name.

2 Selected protocol.

3 Stage name.

4 Select or deselect a ramping phase (= continuous speed/load increase; selectable only when phase name, for example, BRUCE, is highlighted; separately adjustable for each phase).

5 Parameter fields (corresponding to the columns from left to right).
Phase/Stage name.
Stage Time.
Speed.
Grade.
12 Lead Report: First = time of first 12-lead report.
12 Lead Report: Repeat = print interval after first report.
Median Report: First = time of first median report.
Median Report: Repeat = print interval after first report.
BP: First = time of first BP prompt or measurement.
BP: Repeat = interval after first BP prompt or measurement.
Store Median: First = time first median stored.
Store Median: Repeat = interval after first stored median.

6 Click a button to add a new protocol, delete or print an existing protocol.
7 Click button to reset changes.
8 Click a button to add a phase or a graded phase.
9 Click button to delete the selected phase.
10 Click a button to add or delete a stage.

Caution
BRUISE HAZARD — Do not specify BP intervals shorter than two minutes. The BP readings may be incorrect and the tissue might be damaged.

Creating a New Phase

1. Select a blank protocol (for example, *TEST 14*).
2. Click *New Protocol* to display the window with all protocol templates.
3. Select a template from the list.

Editing Stage or Phase Information

1. Click a stage or phase to display the active data fields.
2. Enter data for the stage or phase.
3. To delete this stage or phase, click *Delete stage* or *Delete phase*.
4. To add a stage, click *Add stage*.
5. To add a phase, select a phase. Then click *Add phase* or *Add graded phase*. The new phase is inserted below the selected phase.

Note
New protocols can be created only when the displayed protocol is blank or was deleted.

New phases can be created only when an existing phase is deleted first and when the protocol has less than three phases.

If the stage time in pretest is 0, the pretest phase will automatically begin when the patient starts pedaling.

Run the Final Report

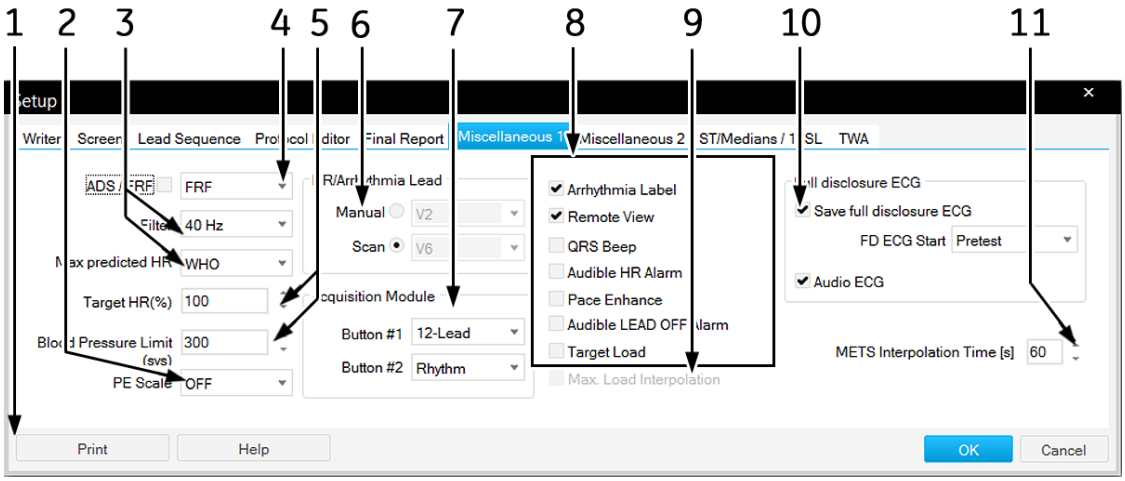
Click *Final Report* for configuration of the report printout.

1. Select the documents to be included in the report.
2. Select a report format.

3. Click *Modify* to edit the report or create a new Configured Report.
4. Select the number of copies.
5. Select the gain.
6. Click *Print Setup* to print the exercise test settings.

Miscellaneous 1 Tab

Click *Miscellaneous 1* to open the window.



1 Controls.

2 Perceived Exertion (PE) Scale. The selected scale will appear in the event list box.

3 Muscle filter frequency and the method for calculation of the *Max. predicted HR*.
- WHO: max. predicted HR = 220 - age
- AHA: max. predicted HR for age < 25: 160, for age > 75: 115, for age between 25 and 75: 160 - (age - 25) x 45/50.

4 FRF or ADS (see A).

5 *Target HR (%)* as a percentage of the max. predicted heart rate and the max. blood pressure.

6 Arrhythmia lead selection mode: Scan or Manual (if Manual: select leads).

7 The reports to be initiated with buttons 1  and 2  on the CC14 acquisition module.

8 Select from the following functions:
- display of *Arrhythmia Labels*
- *Remote View*
- display of *Pace Enhancement* markers
- *Target Load* (value will be calculated and indicated, for bicycle ergometer protocols only)

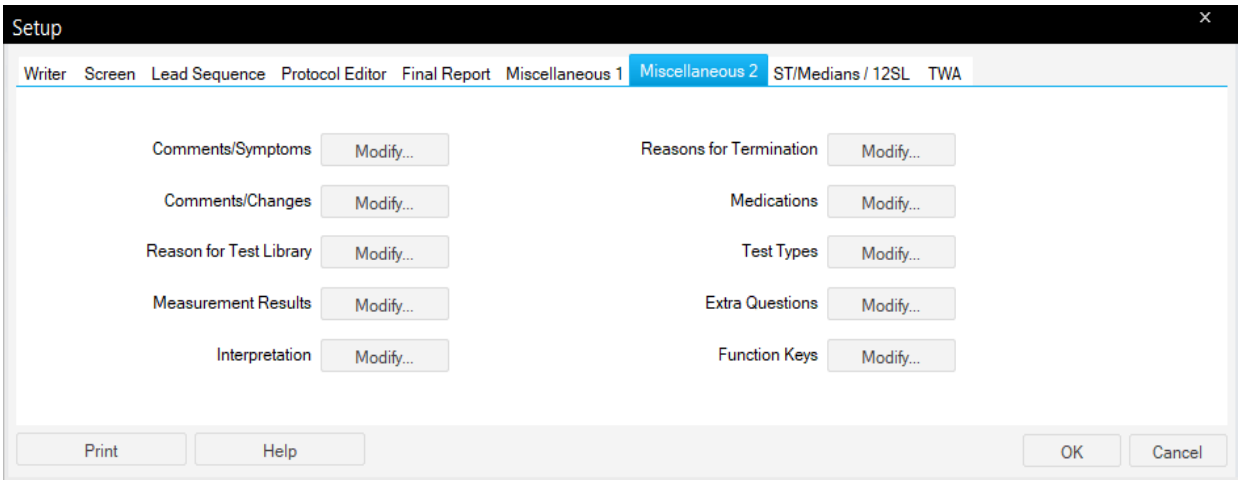
9 *Max. Load Interpolation* function (only possible when the exercise test is performed on a bicycle ergometer). The maximum load is the load of the last completed stage plus the duration of the last stage x load increase/stage time.
Example:
load of the last completed stage: 125 Watts
last stage aborted after 1 minute
load increase: 25 Watts
stage time: 2 minutes
125 W + 1 x 25/2 = 137.5 W
This value is also used to determine the percentage of the target load.

10 *Save full disclosure ECG*, then choose the phase (Pretest or Exercise) when storage of the full disclosure ECG should start, the sampling rate and whether or not you want to record the audio ECG.

11 *METS Interpolation Time*.

Miscellaneous 2 Tab

Click *Miscellaneous 2* to open the window.



Editing the Comments, Test Types, Reason for Test, Reasons for Termination, Medications Library

1. Click *Modify* to open the edit window.
2. Edit, delete or add new statements.

Configuring the Measurement Results

1. Click *Modify* to display the *Measurement Results* window.
2. Select the parameters to be included in the Measurement Results (Test Summary).

Note

ST/HR Index is the maximal change in ST depression as a function of change in heart rate during recovery.

Selection of multiple parameters may cause report header to continue on second page.

Editing the Interpretation Library

Click *Modify* to open the *Interpretation Library* window.

Note

You can edit the eight preset topics. Do not edit the topics, if data will be sent to MUSE. Additional statements can be entered in the window on the right. Click in the blank space below the last statement.

1. Select the topic to edit.
2. Click in the text box and edit the text.
3. Delete or change existing statements or add new ones (a maximum of 20 statements can be entered for each topic).
4. Click the up/down arrows to change the order of topics and statements.

Entering Extra Questions

Click *Modify* to open the *Extra Questions* window.

1. Click in the text box for the first question and type a text (20 characters max.).
2. Select the answer format: *Alphanumeric*, *Numeric*, *Yes/No*.
3. Enter the second question in the same way.

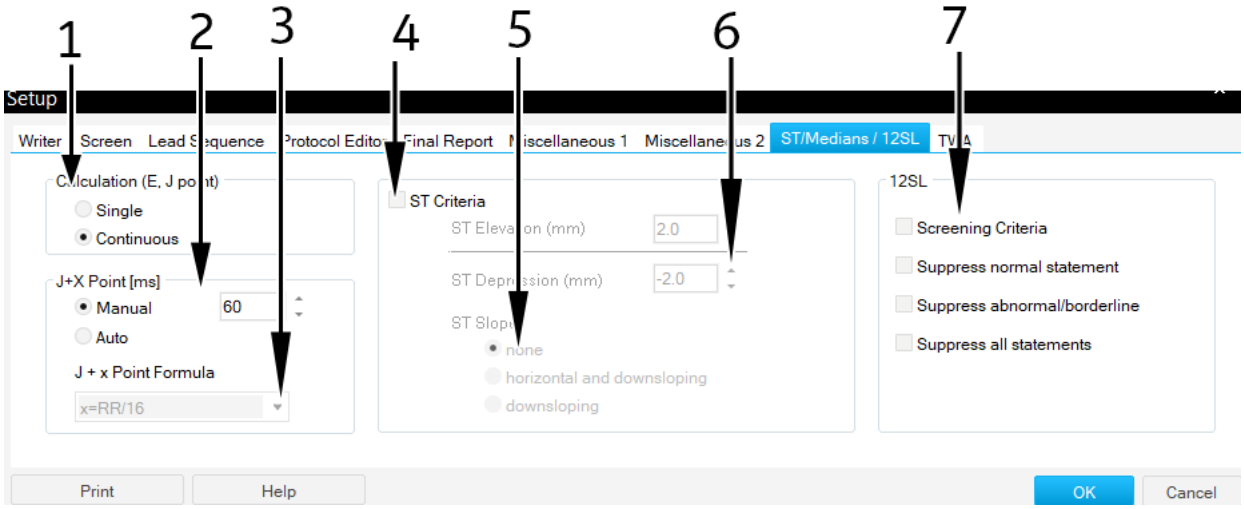
Assigning Functions to the Function Keys

You can assign different functions to function keys F1 through F12 of the PC keyboard. Click *Modify* to open the *Assign function to keys F1 through F12* window. The text boxes display the currently assigned functions.

1. Click the arrow of the function key whose function you want to change.
2. Select a function from the list.

ST/Medians / 12SL Tab

Click *ST/Medians / 12SL* setup ST measurements and 12SL.



1 Select the calculation method for E and J points.

2 Select the calculation method for post-J point.
Manual: set post-J point at D.
Auto: select formula at C.

3 Select the formula for calculation of post-J point.

4 Select ST Criteria.

5 Select ST Slope criteria.

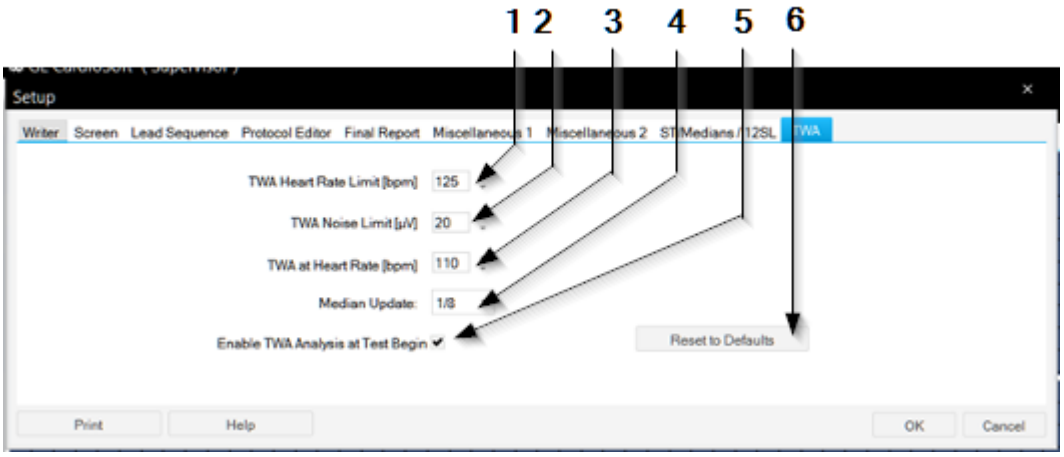
6 Select the max. ST elevation/depression (when the limit is reached, a message appears on the acquisition screen).

7 Select 12SL Criteria.

TWA Tab

Click the *TWA* tab to open the window.

During the exercise test the TWA algorithm analyzes the data in the background. In each of the selected leads, the algorithm calculates the even and odd medians, the TWA value and the noise limit. The data is saved at intervals of 15 seconds. Verify the TWA settings on this tab before the test.



1 Select the *TWA Heart Rate Limit* (TWA values whose HR exceeds this limit are excluded from calculation of the maximum TWA value and are identified with a question mark on the display).

2 Select the *TWA Noise Limit* (TWA values whose noise value exceeds this limit are excluded from calculation of the maximum TWA value and are identified with a question mark on the display).

3 Heart rate: when first reached, the corresponding TWA value is stored separately.

4 Select the update factor.

5 Select the check box to enable TWA analysis at test begin, or deselect.

6 Reset the values to the defaults.

Note

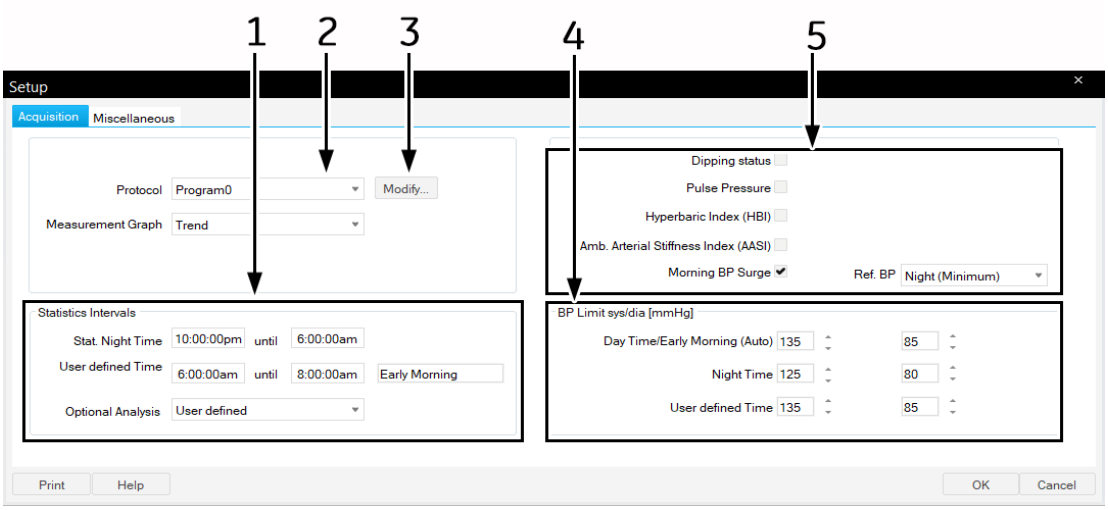
During the test, TWA data records are saved at given points in time. Each TWA data record provides the following information:

- time it was saved
- heart rate
- TWA and noise values for each lead

Ambulatory Blood Pressure Measurement Setup

The settings specific to the ambulatory blood pressure measurement can be entered either from the ambulatory blood pressure acquisition screen where you click *Setup* to display the setup menu, or from the *General* tab of the System Configuration (see "General Tab" on page 12-34).

Acquisition Tab



1 Edit to change the statistical time intervals: Start night time, user defined time, and optional analysis.

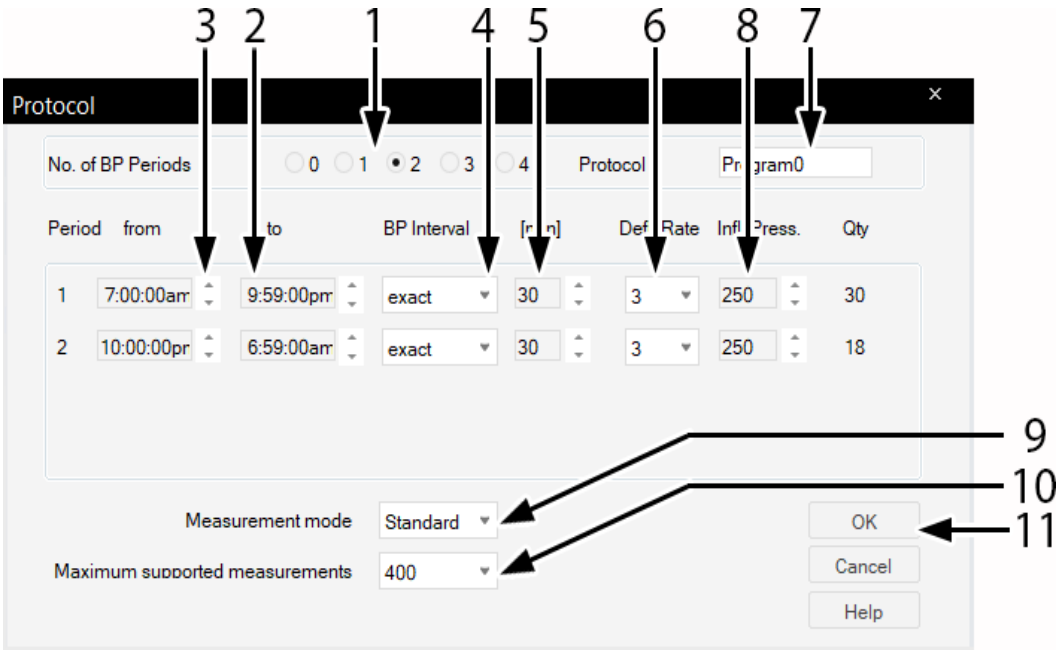
2 Select the measurement protocol.

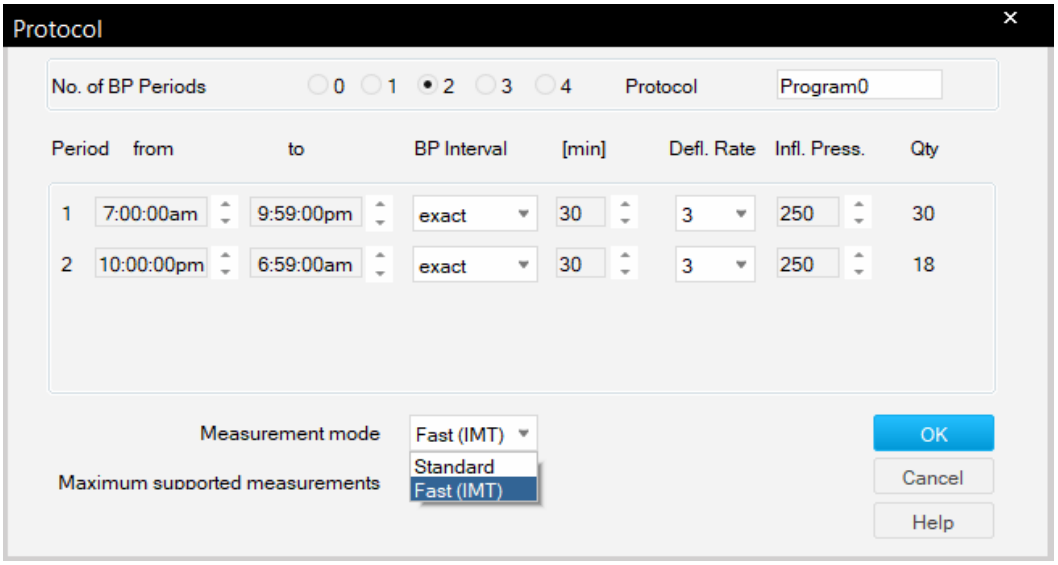
3 Edit the protocol.

4 Edit to change the systolic blood pressure limit for the day time, night time, and user defined time.

5 Select the check box to add the dipping status, pulse pressure, hyperbaric index (HBI), amb. arterial stiffness index (AASI), and morning BP surge to the following report formats on the display and on the printout: measurement results, graphics, statistics summary, day phase, night phase and wake-up phase.

Editing the BP Protocol





Click *Modify* to display the configuration menu.

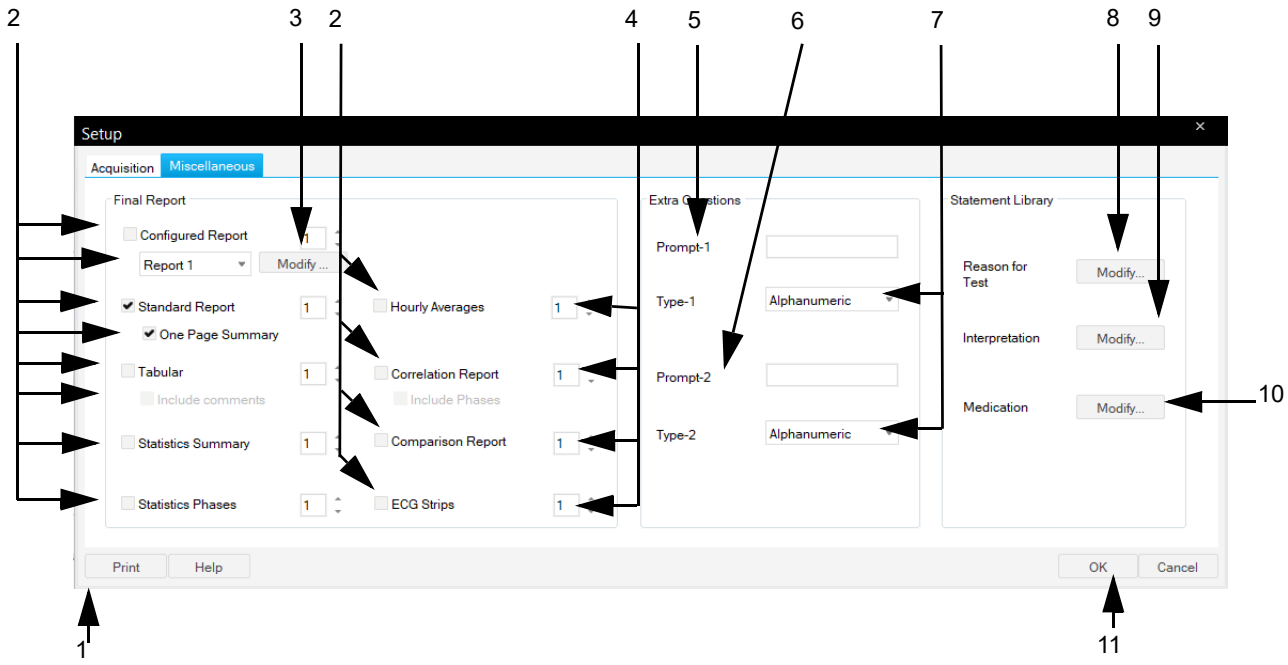
1. Select the number of BP periods.
2. Select the beginning of the period.
3. Select the end of the period.

4. Choose whether measurements are to be taken at exactly or at approximately the selected intervals.
5. Select the BP interval.
6. Select the deflation rate.
7. Enter a name for the protocol.
8. Select the inflation pressure for the first measurement.
9. Select the measurement mode (Standard or Fast (IMT).

   Note: For TONOPORT VI, select Fast (IMT) mode from the drop down menu as a result the report will be generated with Fast IMT. Fast (IMT) mode is only applicable to TONOPORT VI.
10. Configure the maximum supported measurements.
11. Click *OK* to close the window.

Miscellaneous Tab

Click *Miscellaneous* to open the window.



1 Print the ambulatory blood pressure measurement setup.

2 Select documents to be included in the report and configured Report format (The ECG Strips option only applies to TONOPORT IVa.).

3 Edit the Configured Report or create a new one (see "Report Editor" on page 12-6).

4 Number of copies.

5 Extra Question 1 (20 characters max.).

6 Extra Question 2 (20 characters max.).

7 Select the answer format for the Extra Questions.
8 Edit the *Reason for Test* library.
9 Edit the *Interpretation* library.
10 Edit the *Medication* library.
11 Click OK to close the window.

Editing the Interpretation Library

In this window, you can edit the library of interpretative statements. You can enter a maximum of 12 statements.

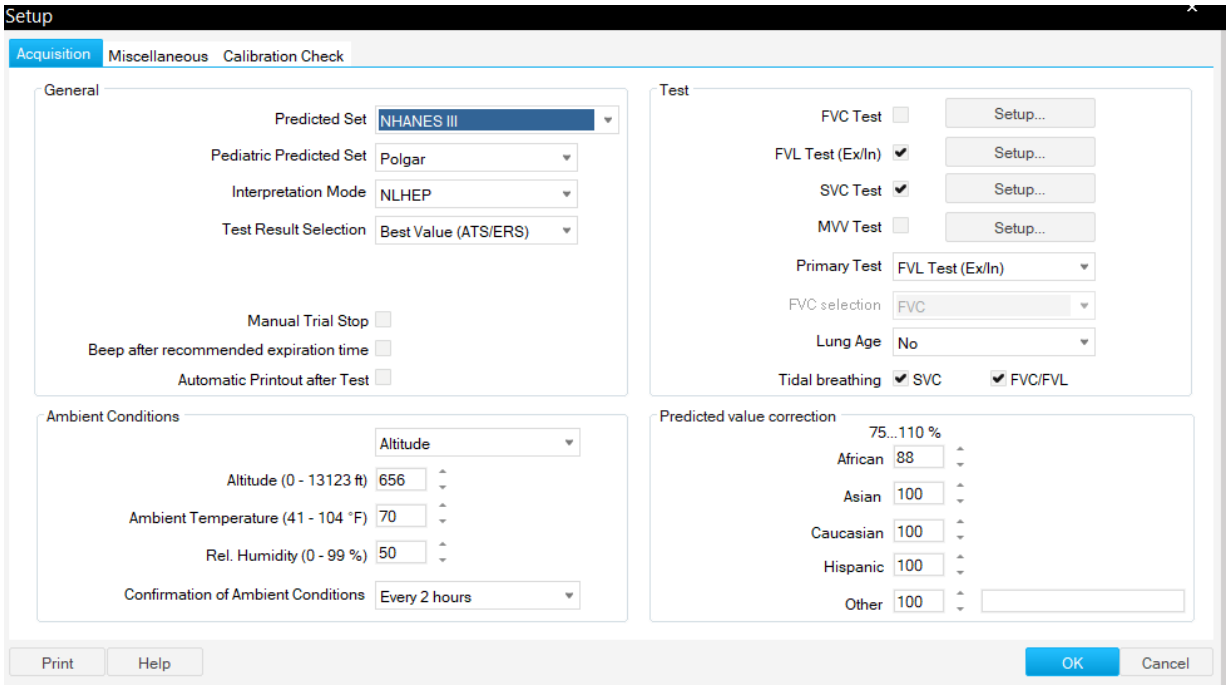
1. Click *Modify* to display the *Interpretation* library.
2. Double-click an interpretation statement to edit it.
3. Use the icons at the bottom of the window to:
   - Open (++) or close (- -) folders.
   - To insert chapters, click on  icon.
   - To insert lines, click on  icon.
   - To delete chapters, click on  icon.
   - To sort text alphabetically, click on  icon.

Spirometry Setup

The settings specific to spirometry can be entered either from the spirometry acquisition screen where you click *Setup* to display the setup menu, or from the *General* tab of the System Configuration (see "General Tab" on page 12-34).

Acquisition Tab

The *Acquisition* tab is already on top.



Fields	Description
General	
Predicted Set	Click to select the predicted values for adults.
Pediatric Predicted Set	Click to select the predicted values for children.
Interpretation Mode	Select/deselect the system interpretation mode.
Test Result Selection	Select the Test Result Selection (Best Value/Best Trial).
Manual Trial Stop	Select this check box, to stop tests manually.
Beep After Recommended Expiration Time	Select this check box, beep after the recommended expiration time.
Automatic Printout After Test	Select this check box, if you want automatic printout after the test.
Ambient Conditions	
Ambient Condition	Change the Ambient conditions input mode between altitude and Atmospheric pressure.
Altitude (0 - 13123 ft)	Enter altitude/atmospheric pressure.
Ambient Temperature (41 - 104 °F)	Enter ambient temperature.

Relative Humidity (0 - 99%)	Enter humidity.
Confirmation of Ambient Conditions	List box for confirmation of Ambient conditions (Before Each Test/Every 2 Hours/Daily/Via Setup)
Test	
Test	Check boxes for selecting/deselecting test types.
Setup	Button Setup opens a new popup window and parameters for test can be selected. See section "Parameter Selection".
Primary Test	Select primary test.
FVC Selection	Select FVC/FEC6.
Tidal Breathing	Select SVC and/or FVC/FVL.
Predicted Value Correction	Enter ethnic correction.

Note

Check the entered ambient conditions each day. The program needs this information for BTPS correction (Body Temperature Pressure Saturated), for example, the measuring values are referred to an ambient pressure and saturation with water vapor at a body temperature of 98.6 °F.

Exiting the spirometry setup menu with *OK* confirms all data. At the same time, date and time on the acquisition screen is updated.

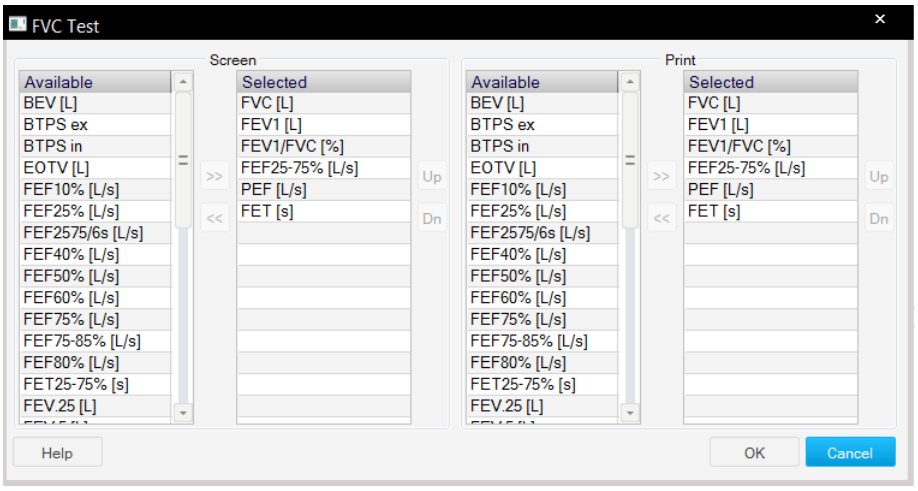
Parameter Selection

Click *Setup* to open a window for selecting the parameter to be calculated. Different parameters can be selected for display and evaluation.

- To select parameters, choose a parameter in the "Available" list and click on **>>** to transfer the parameter to the "Selected" list.
- To deselect parameters, choose parameters in the Selected list and click on **<<** to transfer to Available list.
- To scroll up and down the list, use the **Up** and **Dn** buttons.

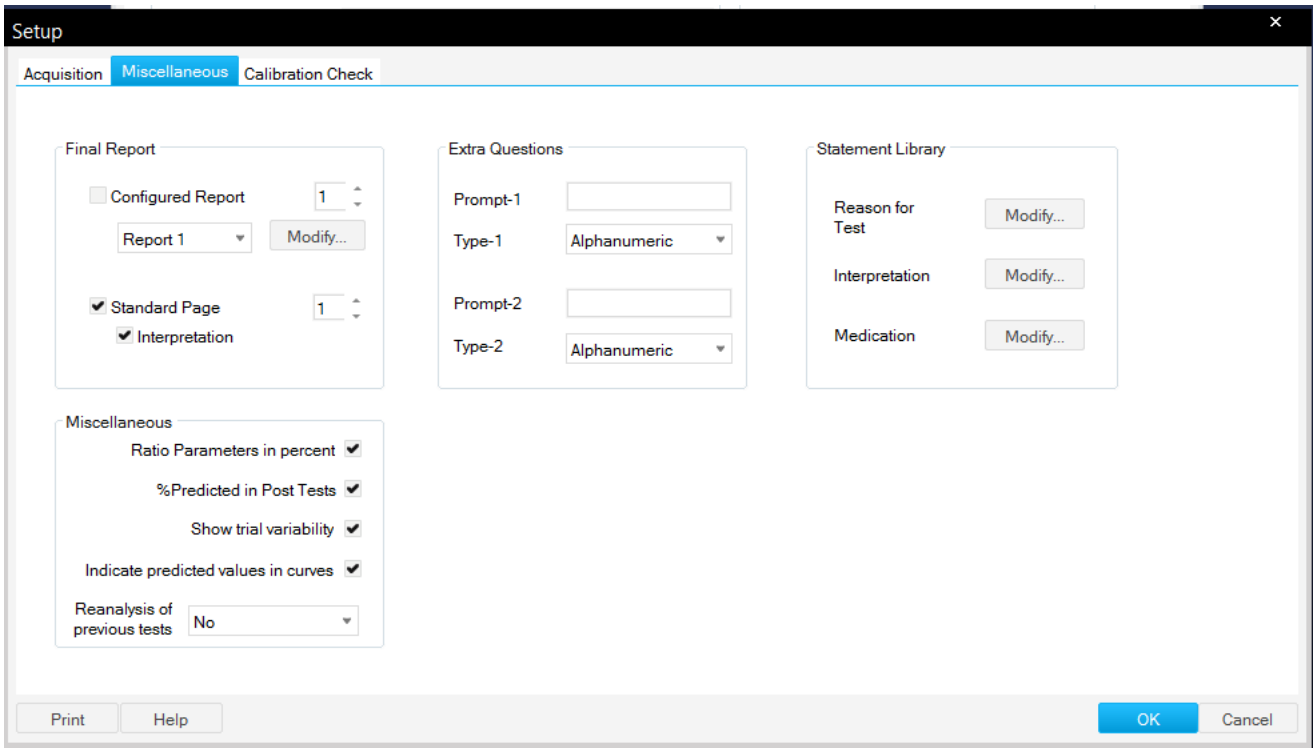
Note

Different parameters can be selected for each test.



Miscellaneous Tab

Click *Miscellaneous* to open the window.



Fields	Description
Final Report	Select the documents to be included in the report.

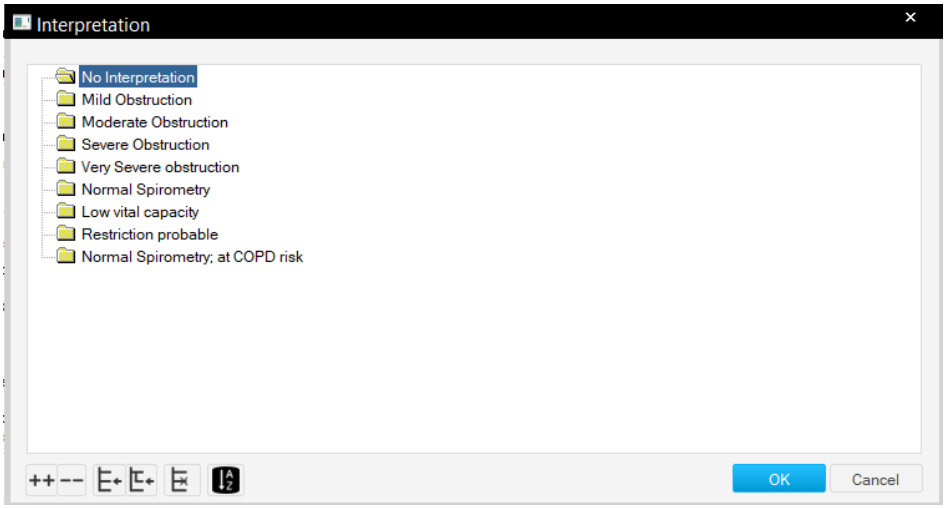
Configured Report or Standard Page	■ Select the configured report. ■ Click Modify to edit the configured report or create a new one. See section "Report Editor" on page 12-6. ■ Select number of copies.
Extra Questions	
Prompt-1 / Prompt-2	Enter the extra question (max 20 characters).
Type 1 / Type 2	Select the answer format.
Statement Library	
Reason for Test	Click *Modify* to edit the reason for test library. You can edit, delete or add new statements.
Interpretation	Click *Modify* to edit the interpretation library. See section "Editing the Interpretation Library" on page 12-4.
Medication	Click *Modify* to edit the medication library. You can edit, delete or add new statements.
Miscellaneous	
Ratio Parameters in percent	Select this check box to display the ratio parameter as a percentage value
% Predicted in Post Tests	Select this check box to display the percentage deviation from predicted, remove the check mark by clicking again
Show trial variability	Select this check box to show trial variability
Indicate predicted values in curves	Select this check box to indicate predicate values in curves
Reanalysis of previous tests	List box for enabling/disabling the Reanalysis or previous tests of the patient on configuration change (No/With confirmation)

After the required settings are defined, click *OK*.

Select *Print* to print the spirometry test setup.

Editing the Interpretation Library

In this window, you can edit the library of interpretative statements. You can enter a maximum of 12 statements.



1. Click *Modify* to display the *Interpretation* library.
2. Click a line to highlight it.
3. Click a second time to enable the edit mode and enter your changes.
4. Use the icons at the bottom of the window to:
   - Open (++) or close (- -) folders.
   - Insert chapters.
   - Insert lines.
   - Delete chapters.
   - Sort text alphabetically.

Calibration Check Tab

The American Thoracic Society (ATS) recommends that the spirometer calibration be checked on a regular basis. Owing to the ultrasound technology used in the TrueFlow Sensor, the device requires no calibration, even if used frequently.

To comply with the recommendations, you can check the calibration as follows:

Note

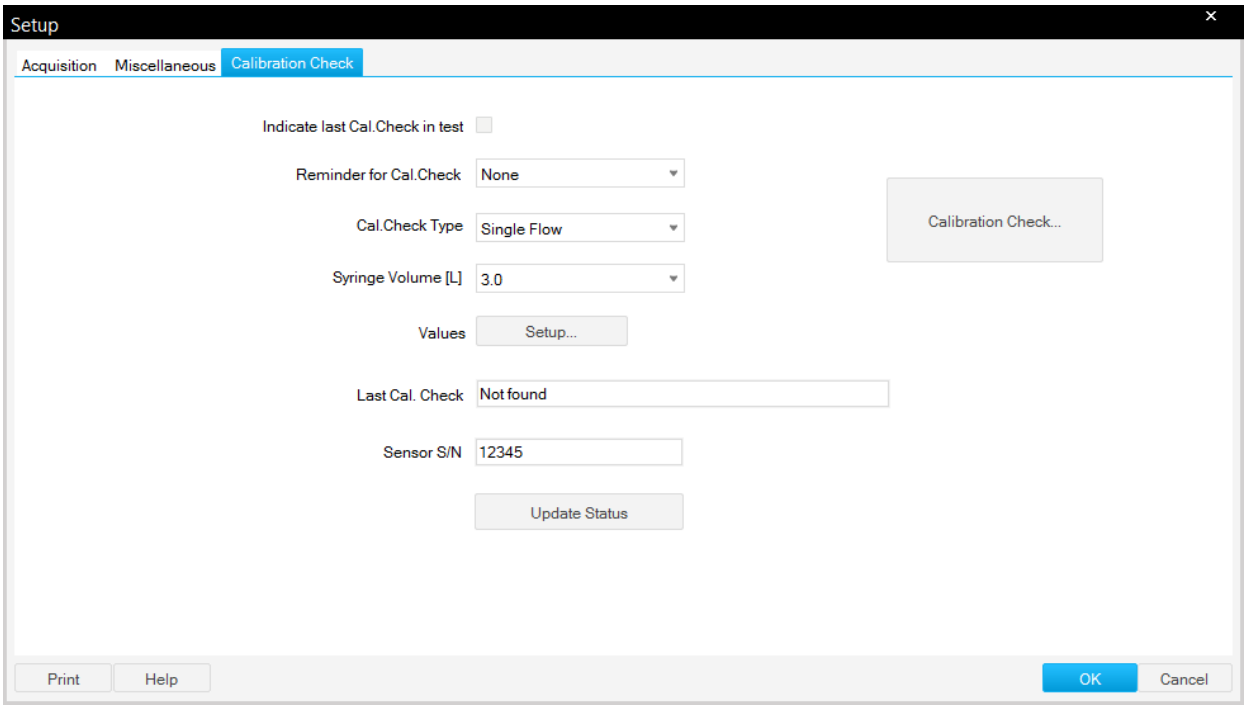
You need the Spiro-SP calibration adapter and a calibration syringe.

Using the calibration adapter, connect the sensor to the syringe as shown. Ensure that the piston is fully inserted and at the stop position.



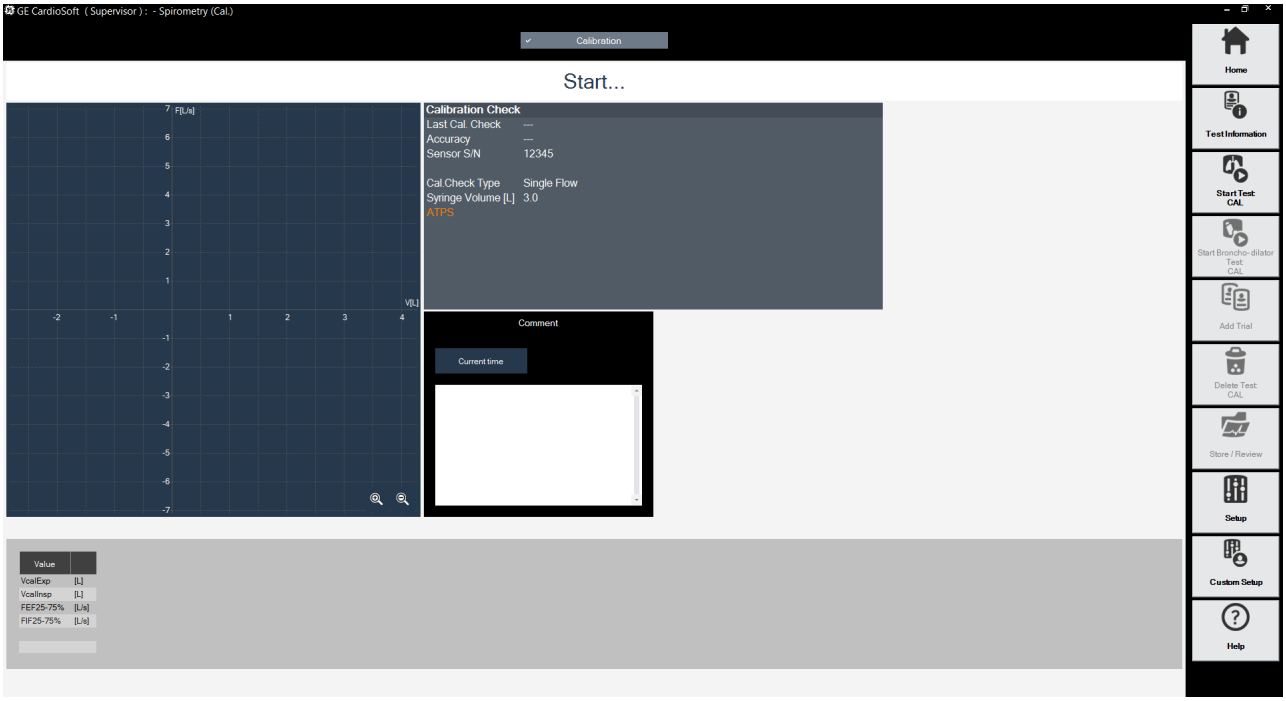
Calibration can be done from system configuration or during the test by clicking on the setup button.

Click *Calibration Check* to open the window.

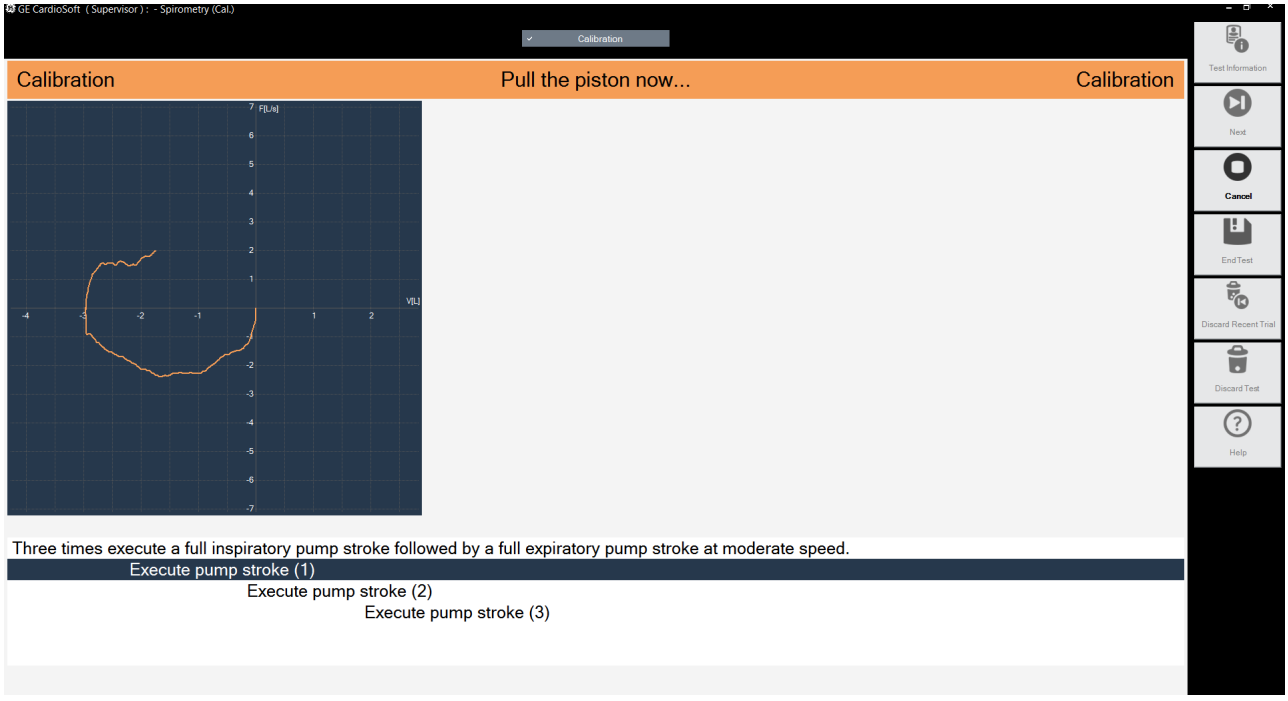


Fields	Description
Indicate Last Cal Check in test	Select this check box to indicate the last calibration check data in the test.
Reminder for Cal. Check	Enable the Reminder for calibration check (None/daily/Weekly/Monthly/quarterly/Every six months).
Cal. Check Type	Select the calibration check type.
Syringe Volume (L)	Select the volume of the Syringe in liters used for calibration.
Values	Open a window for selecting parameters. See section Parameter Selection for reference.
Last Cal. Check	Displays the last calibration check data.
Sensor S/N	Enter the serial number for the sensor.
Update Status	Update the status of calibration.
Calibration Check	Click to start the calibration.

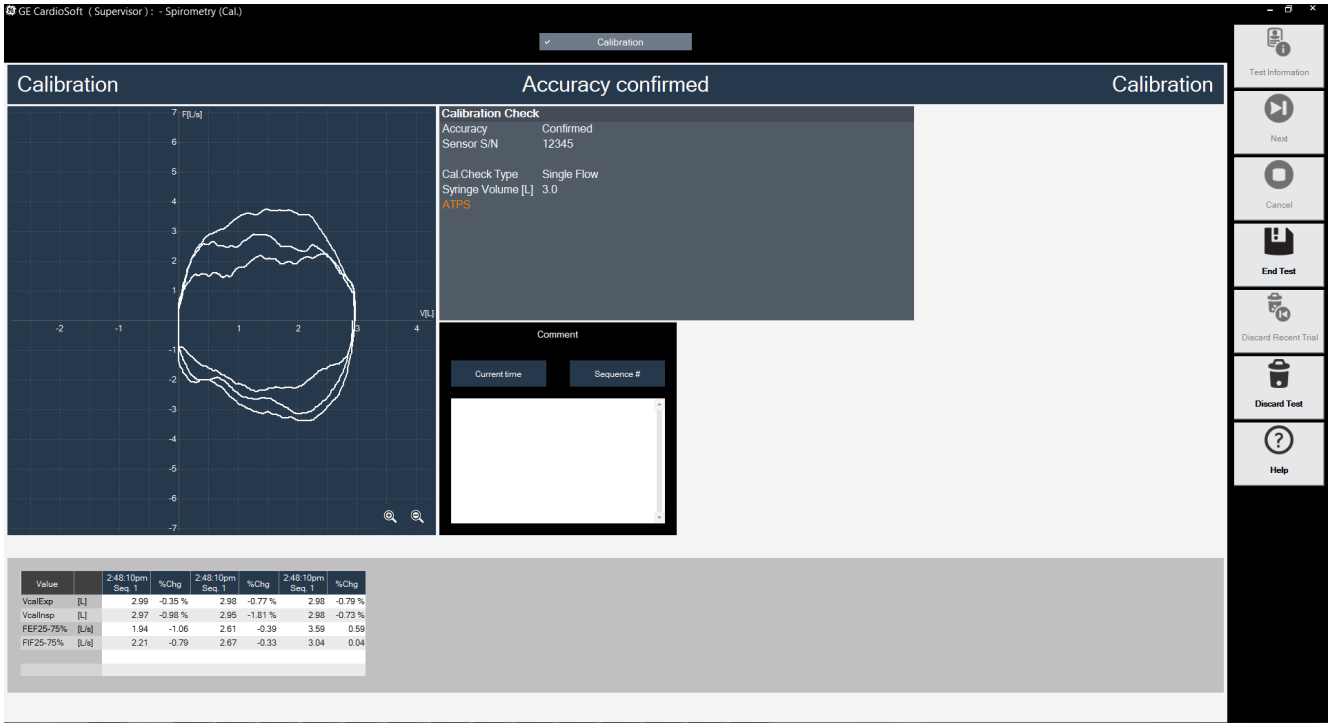
Click *Calibration Check*.



Click *Start Test Cal* and follow the instructions as shown on the screen.

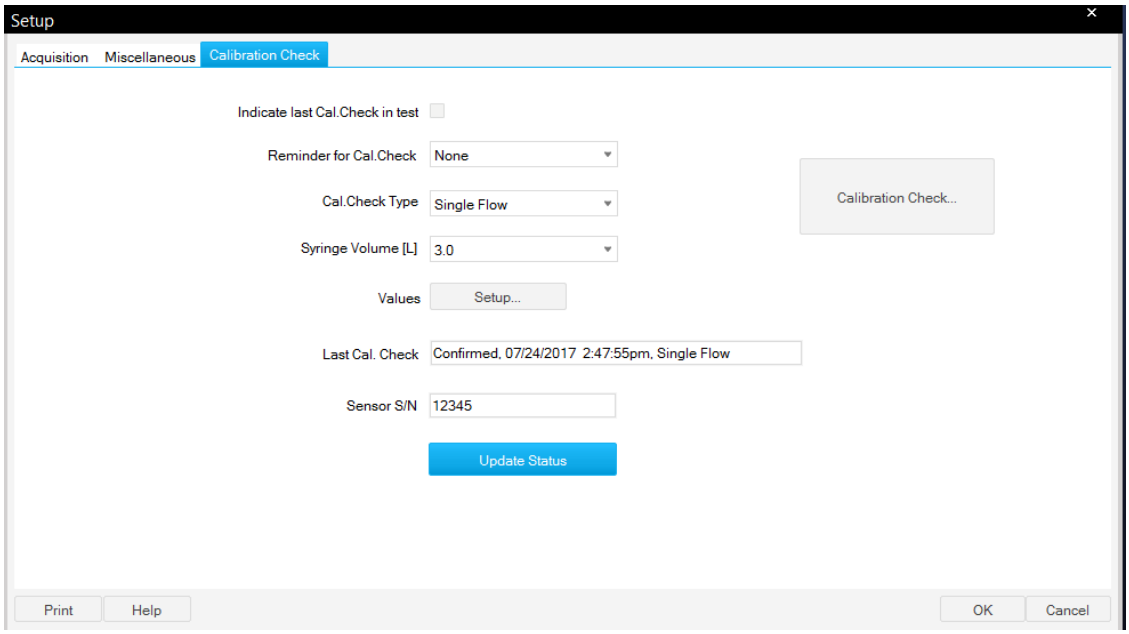


Click *End Test* for the application to confirm the accuracy.



After the calibration check is finished, the data will be updated in the configuration.

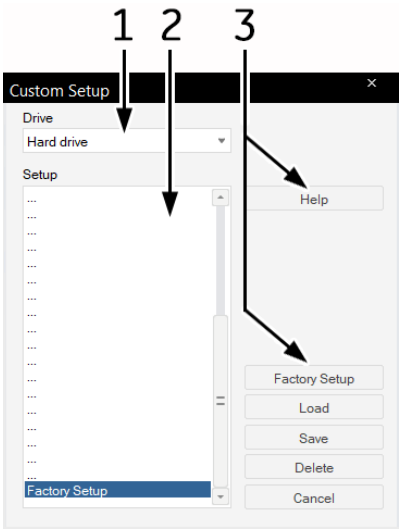
Click *Update Status* to view the last calibration check values.



Custom Setups, Factory Setup

The program allows you to save, load, and delete your personal settings for the different test modalities. From the same menu, you can restore the factory defaults.

You access the setup menu by clicking the *Custom Setup* button on the acquisition or pre-acquisition screen, or from the *General* tab of the System Configuration (see "General Tab" on page 12-34).



1 The drive.

2 Saved custom setups.

3 Factory Setup, Load, Save, Delete, Cancel, and Help a setup.

Save

1. Click *Save*.
2. In the *Save Setup* window, select the target drive from the list.
3. Select a line in the *Setup* window A.
4. In the *Save As* box, enter a name.
5. Click *Save* to save the setups of all modalities.

Load or Delete

1. Select the drive.
2. Select the name.
3. Click *Load* to load the setup or click *Delete* to delete the setup.

Note

Be sure to save the current setup before loading one of the stored setups, or your modifications will be lost.

With some bicycle ergometers, restoring the Factory Setup will delete your own exercise test protocols and phases.

The following parameters cannot be loaded, stored or reset to the factory defaults.

Exercise Tests

- Remote View

Spirometry Tests

- ambient conditions

System Configuration

- all settings on the *General* tab

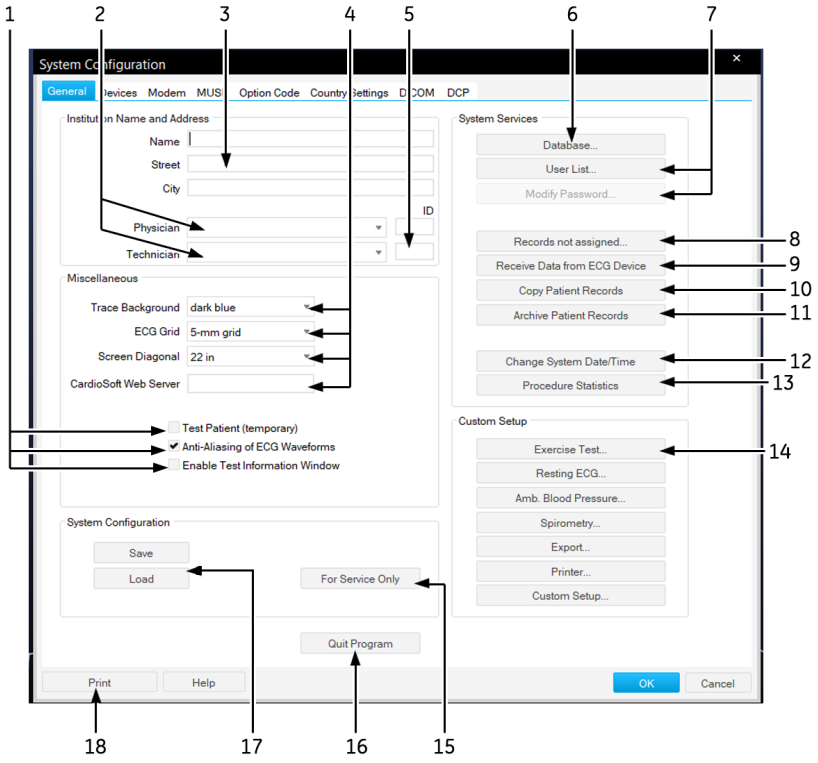
Load the Factory Setup

1. Click *Custom Setup* on the acquisition or pre-acquisition screen, or on the *General* tab of the System Configuration.
2. Scroll to the bottom of the list box.
3. Select *Factory Setup*.
4. Click *Load* to load the setup.

System Configuration

Click *System Configuration* on the initial screen to display the menu.

General Tab



1 ■ *Test Patient*: Select check box to run a test using simulated patient data. Select the function each time before starting a simulated test.

WARNINGS
INTERPRETATION HAZARD—Select the simulated patient data for demonstration purposes only to avoid misinterpretation of the data.

■ *Anti-Aliasing*: Select check box to smooth the ECG signal traces.
■ *Enable Test Information Window*: Select check box to automatically display the *Test Information* window on the acquisition or pre-acquisition screen.
■ Select check box to automatically delete tests saved to an archive.

2 Enter or select the default physician and technician names (the names will appear on the *Test/Personnel* tab).

3 The name and address of the hospital or practice (information appears on the printed reports).

4 ■ *Trace Background*: Click to select the background for the signal traces.
■ *ECG Grid:* Select the grid format for the displayed ECG.
■ *Report ECG Grid:* Select the grid format for the printed ECG.
■ *Screen Diagonal*: Select the size of your PC monitor (*custom*, see "Adjusting the Screen Size for Widescreen Monitors" on page 12-37).

5 The physician and technician IDs. When sending data to a MUSE system, be sure to match User ID numbers assigned at the MUSE system to User ID numbers assigned at the CardioSoft unit.

6 Settings for temporary use of the offline (local) database (see "Working Temporarily with the Local Database" on page 9-8).
Click to enter a percentage value for the minimum free hard drive storage capacity. You will be alerted when the capacity drops below this value.

7 ■ *User List*: Click to define the users, groups and privileges for individuals working with the system (see next page).
■ *Modify Password*: Click to modify the current user's password (not with Windows user list).

8 Display the assignment list (available only when unassigned tests exist, see"Assignment List" on page 12-40).

9 Transfer resting ECGs (see "Receiving Resting ECGs from Other ECG Devices" on page 12-38).

10 Copy patient records to another medium. The patient records remain stored in the local database (see "Copying Patient Records" on page 12-40).

11 Archive patient records not currently used on an external medium (see "Archiving Patient Records" on page 12-41).

12 Change the system date and time (see "Changing System Date and Time" on page 12-41).

13 Run a statistical analysis of all tests performed with the system (see "Procedure Statistics" on page 12-41).

14 Display the *Custom Setup* screens for
■ Resting ECG (see "Resting ECG Setup" on page 12-3)
■ Exercise Test (see "Exercise Test Setup" on page 12-8)
■ Spirometry (see "Spirometry Setup" on page 12-23)
■ Ambulatory Blood Pressure (see "Setting Up the Ambulatory Blood Pressure Monitor" on page 7-5)
■ Export (see "Settings" on page 9-7)
■ Printer (see "Printer Settings" on page 12-42)
■ Custom Setup (see "Custom Setups, Factory Setup" on page 12-33).

15 Access the service screen (requires Service password).

16 Save or load the System Configuration.

17 Quit the program.

18 Print the System Configuration.

Note

If you cannot remember the supervisor password, contact the GE Healthcare Technical Support or your local Service Representative.

Adjusting the Screen Size for Widescreen Monitors

1. Select *custom*.
2. Click [...].
3. Adjust the height of the displayed window to 10 cm, using a ruler.
4. Adjust the width in the same way.
5. Clear the window.

User Administration

User List on the *General* tab displays the list of all registered system users if you select the *Enable Password Function* check box in the preceding window. You can edit user data with *Modify* (select name first), delete a user with *Delete* or register a new user with *New*.

If you enable *Use Windows User List*, the user list of the specified *Windows domain* displays.

Windows User List

This feature allows you to display the user list of the Windows domain and authorize these users to access the system. The local user list will be deleted.

1. Click *Set Administrator User Name* to log on as administrator.
2. Select a user from the list.
3. Register the user with the appropriate privileges.

Note

Record the administrator's user name and assign the appropriate privileges.

Call up the capture settings from the *User List*. The selected events will be captured. The records are saved to the *Event Log*. Open the *Event Log* with *Start ->Programs ->General Administration ->Event Log*. Select the capture item in the *Event Log*. The source for all entries from this application is *CARDIO*. These details are shown after double-clicking the entry:

- event category
- user
- cart/device number
- patient ID
- test type
- test date
- test time

Note

Only the System Administrator is authorized to perform these administrative tasks.

Click *New* to display the user registration window.

1. Enter the user name and ID number. If you enter the last name before the first name, insert a comma in between. Otherwise the name entered first becomes the first name and the name entered second becomes the last name, when the user is registered in the MUSE system. MUSE accepts first names with a maximum length of 10 characters, last names must not be longer than 16 characters. When sending data to a MUSE system, be sure to match User ID numbers assigned at the MUSE system to User ID numbers assigned at the CardioSoft unit.
2. Select the user group.
3. Select the user's custom setup.
4. Select the user's privileges.

   Edit Data: user is authorized to edit test and patient data.

   System Configuration: user is authorized to edit the *System Configuration*.

   Setup: user is authorized to edit the test settings.
5. Enter a password that is at least six characters long. Do not use any special characters.
6. Select the *External User* check box if you wish to receive data from remote test stations (at the sending stations, enter the addressee's name and password).

Note

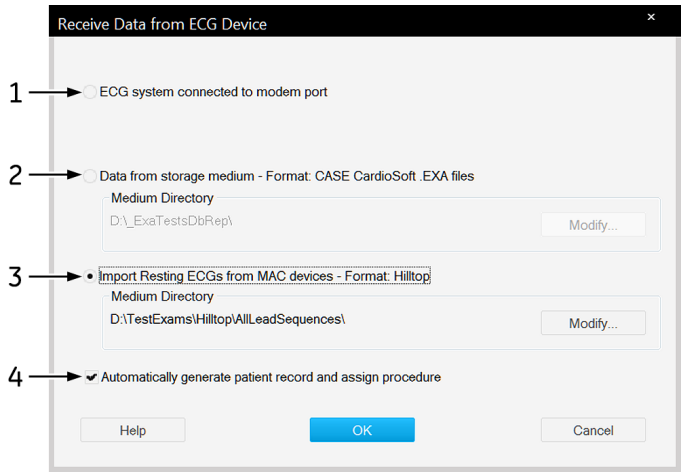
Only the System Administrator is authorized to perform these administrative tasks.

Receiving Resting ECGs from Other ECG Devices

With the *Receive Data from ECG Device* function, resting ECGs acquired with other GE Healthcare ECG devices can be transferred to the local database.

Note

If an ECG is received without patient ID (not even blanks), it will automatically appear in the list for manual assignment with the special patient ID “000000“.



1. Click *Receive Data from ECG Device* on the *General* tab to display the setup window.
2. Select the transmission modality.
   - ECG system connected to modem port = CardioSoft
   - ECG recorder connected to modem port = MAC ECG recorder. If you wish to accept only procedures from registered physicians, select the check box. The physician's last name must be entered at the MAC 1600 before acquisition of the resting ECG. The same physician's name must be registered in the user list in the physician group.
   - MAC ECG recorder connected to serial interface: Enter the baud rate (19200 is preferred; see Technical Specifications of the equipment used) and the port.

Note

Sometimes, when a patient ID has not been entered, ECG recorders may send a series of blanks instead of a patient ID.

A device number (for example, 12) can be entered at the ECG recorder: to do so, type hospital %12% at Hospital/Practice Name.

3. Select this option to receive data from a storage medium and specify the directory.
4. Select this option button to receive MAC ECGs from a disk or memory card (SD card) and specify the directory. Then insert the disk or memory card into the appropriate drive.
5. Select or deselect to automatically assign tests to a patient, or to enter tests in a list from which they can be assigned manually.

   Conditions for automatically assigning tests to patients:

   - The patient ID is new and is transferred to the database together with the patient data of the incoming test.

- The patient ID already exists and last name, first name as well as the date of birth are identical with the information of the incoming test. Blank data fields are considered as identical.

If these conditions are not met, the test will appear in the list for manual assignment, even though automatic assignment has been selected (see next page).

6. Click *OK* to initiate the transfer.

A progress indicator appears. Observe the instructions displayed on screen.

7. Press *Copy* on the ECG recorder or send stored ECGs (see separate Operator Manuals that come with the ECG recorder).
8. Click *Cancel* to terminate the transfer.

Note

It is possible to simultaneously send the ECGs from up to 4 ECG recorders via modem to the system. To utilize this feature, an extra PC is required as the communications server. This server is part of a network through which the ECG can be routed to the system or to a MUSE system database. For details, contact GE Healthcare Technical Support or your local Service Representative.

Assignment List

In the assignment list, you will find all tests that were not automatically assigned to a patient record. This list appears whenever incoming ECGs cannot be assigned, or you can display it manually from the *General* tab (see "General Tab" on page 12-34).

1. Click the patient record.
2. Click *Find* to select the patient or enter a new patient.
3. Click << to assign the patient record to the patient.

Copying Patient Records

With the *Copy Patient Records* function, patient records can be copied from the local database to a removable media or a network drive, or they can be moved from a removable media or network drive to the local database. When "moved", the data record will be deleted from the source medium.

Click *Copy Patient Records* on the *General* tab to display the setup window.

1. Select the patient.
2. Select the patient records to copy.
3. Select the target drive and/or directory.
4. Click >> to copy patient records TO USB drive or SD card.

5. Click << to move patient records from a USB drive or SD card.

Archiving Patient Records

With the *Archive Patient Records* function you can export patient records not currently used to an external medium. The date and test type remain included in the patient record list. An asterisk * identifies archived patient records.

Do not copy the data to the root directory (for example, d:\), create a subdirectory (for example, d:\data\).

If you want to view an archived patient record, the system will indicate the storage medium. Archived patient records can be transferred to the MUSE database system only after they have been restored.

Click *Archive Patient Records* on the *General* tab to display the setup window.

1. Enter a date: patient records older than this date will be archived.
2. Click *Archive*.
3. Insert the storage medium and, after archiving, label it with the number displayed.
4. Select the target drive or directory.
5. Click *OK*.

Note

When working in a network environment, quit the program before archiving patient records. Run a backup of all data before archiving them. Each file must be smaller than the capacity of the storage medium.

Changing System Date and Time

Click *Change System Date/Time* on the *General* tab to display the setup window.

Access to the *Date/Time Properties* dialog is restricted to authorized system users.

Procedure Statistics

Click *Procedure Statistics* on the *General* tab to display the setup window.

1. Enter the date range for the statistical analysis.
2. Select the period (month, quarter, and year).
3. Click to calculate the statistics.

4. Click to export the data to Microsoft Excel.

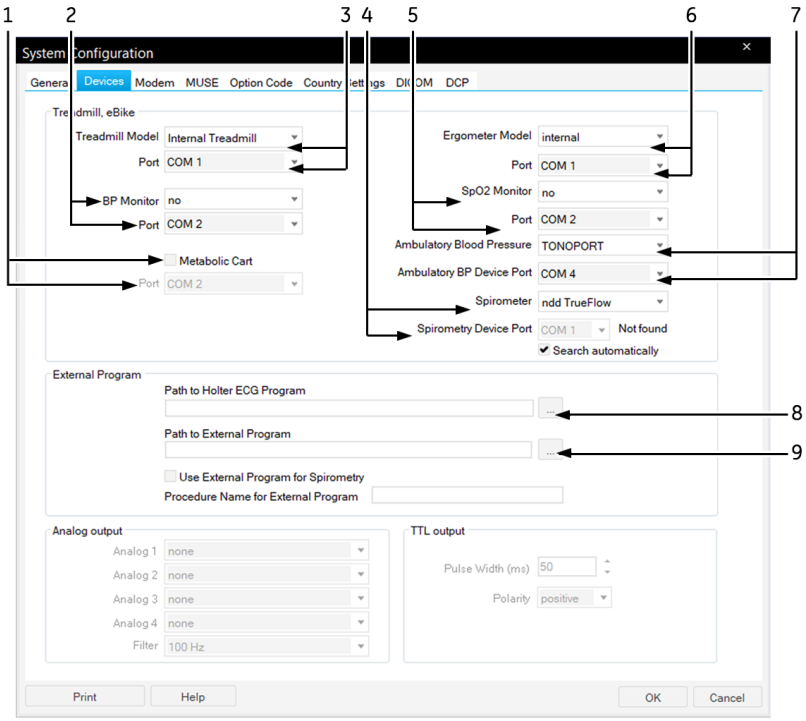
Printer Settings

Click *Printer* on the *General* tab, page 12-35 to display the setup window.

1. Select the printer.
2. Optional: Select the *Color Printouts* check box.
3. Define the colors.
4. Select the ECG grid format.
5. Click *Default* to restore the initial settings.
6. Click *OK* to clear the window.

Devices Tab

Click *Devices* to open the window.



1	Select check box, then select a port for the metabolic cart.
2	BP monitor model and the port.
3	Treadmill model and the port.
4	Spirometry device type and the port (*none* indicates that the modality is inactive).

5 SpO_2 monitor model and the port.

6 Ergometer model and the port.

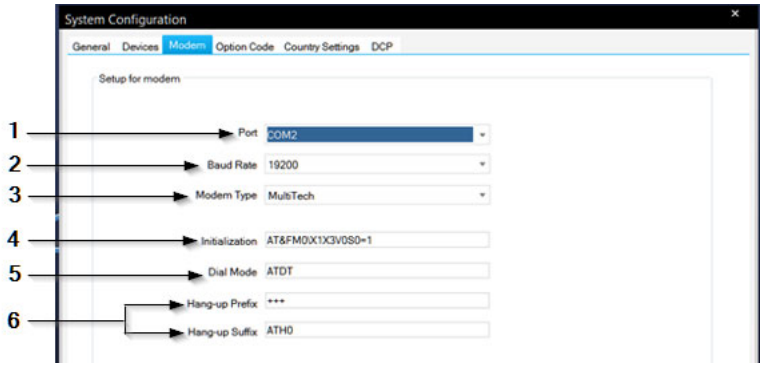
7 Ambulatory BP device and the port (*none* indicates that the modality is inactive).

8 Enter or select the path to the Holter ECG program.

9 Select an external program for spirometry, enter or select the path.

Modem Tab

Click *Modem* to open the window.



1 Modem port.

2 Baud rate (same baud rate at sending and receiving units).

3 Modem type.

4 Initialization string (entered automatically for *MultiTech* and *ELSA* modems). Initialization string for other modem types (for example, MultiTech 56K): AT&FM0\X3V0S0=1

5 Dial mode (pulse/touch tone dialing).

6 *Hang-up Prefix* and *Hang-up Suffix*.

Warning
PATIENT HAZARD — All modems connected to the system must meet the requirements of IEC 60950. The specific regulations valid in your country must also be observed. The modem must be installed within the medical location, but not in the patient vicinity.

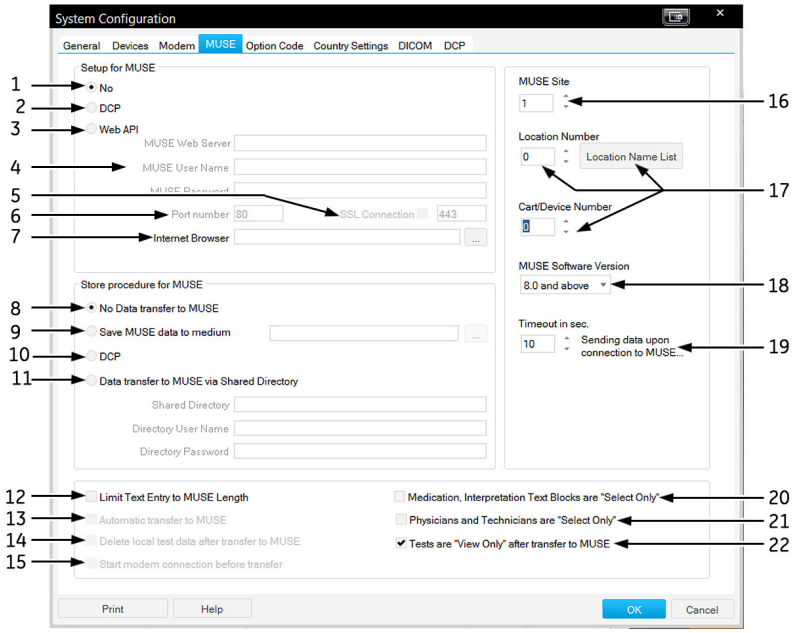
Note
For *Dial Mode, Hang-up Prefix and Hang-up Suffix,* please refer to the user manual of your modem.

MUSE Tab

Click *MUSE* to open the window.

Note

CardioSoft is compatible with the following versions of the MUSE system: 7.1 or 8.0 and above.



1 Select No to disable order download from a MUSE system.

2 Select DCP to retrieve orders from a MUSE system via the DCP protocol.

3 Select MUSE Web API to retrieve orders from a MUSE system using the MUSE WebAPI..

4 Information required for MUSE Web communication with the MUSE.

5 Select, if SSL is configured at the MUSE Web server.

6 Port number.

7 Configure the Internet browser. Enter the path to the Internet browser to start the MUSE Browser. Both the Internet browser (Internet Explorer, version 4.0 and later) and the Acrobat Reader program must already be installed. The Internet browser must be set up for proper communication (web address of the MUSE system, etc.). Contact GE Healthcare Service for details.

8 ECG data is not transferred to a MUSE system.

9 Copy data to MUSE system via disk.

10 Select DCP to transfer examination records to a DCP server.

11 Select to transfer data to a MUSE system via a network, using a shared directory.

12 Limit entered text to the maximum length accepted by MUSE.

13 Automatically transfer each test or each modification to a test to the MUSE system.

14 Delete patient records from the local database after transfer to a MUSE system.

15 Start the modem connection before the transfer.

16 MUSE Site number.

17 Location and device number. Display the location name list.

18 MUSE software version.

19 Set the maximum transmission time before timing out.

20 Restrict adding text in the *Medication* and *Interpretation* windows.

21 Restrict adding text in the *Physicians* and *Technicians* windows.

22 Restrict editing tests after transfer to the MUSE system.

Note

Use the GE Healthcare network installation kit to ensure all patient isolation requirements are met.

A GE Healthcare Service Representative is required to configure the MUSE system.

Only resting ECGs and exercise tests can be transferred to the MUSE system.

MUSE does not support the following resting ECG information:

- Hospital name, street, QT dispersion.
- Arrhythmia labels for each QRS complex.
- Vector loops.
- Lead-related measuring values (Tabular Summary).
- Full Disclosure ECG.

MUSE does not support the following exercise test information:

- Sokolov index, QT dispersion.
- Full disclosure ECG.
- Arrhythmia review.
- ST/HR slope.
- ST/HR index.
- Waterfall.
- TWA trends.
- TWA medians.

Option Code Tab

Click *Option Code* to open the option code window. If you have purchased additional software options, enter the option codes to activate the software options. The code numbers are given on the supplied option code sheets or on a disk.

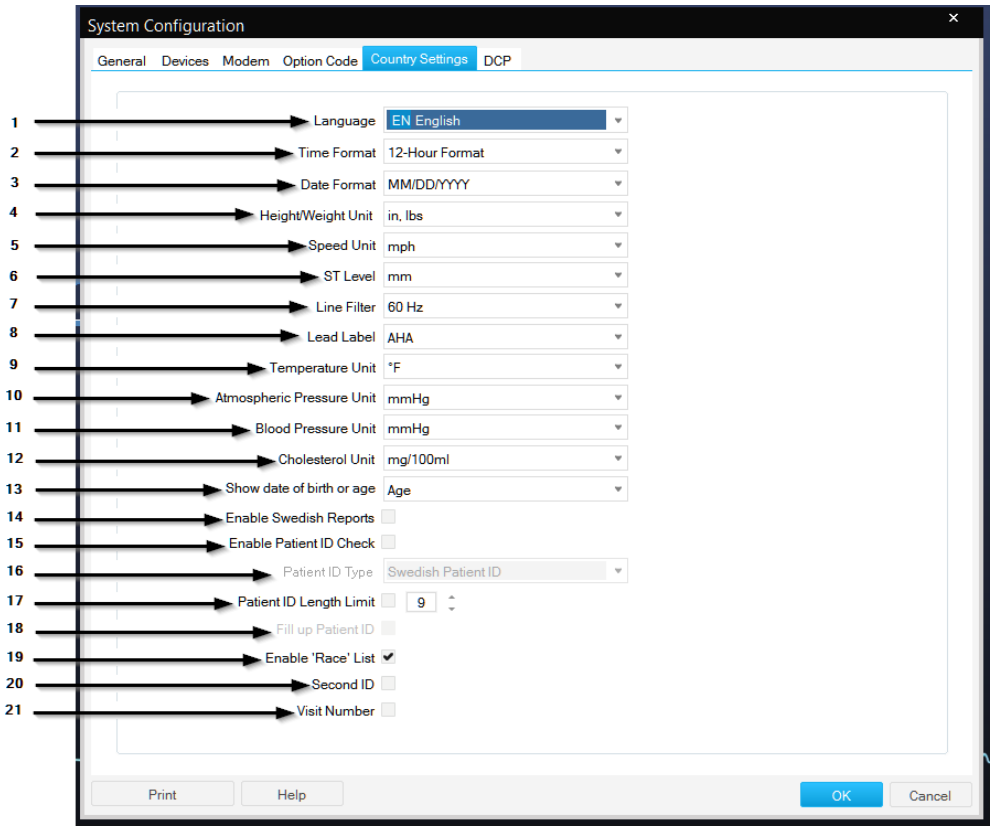
1. Click *Modify*.
2. Click *Yes* to confirm.
3. Enter the option code in the appropriate field or click *Load* to load the option code from disk.
4. Optional: To enable an option for a limited period of time, click the icon and enter the expiration date.

Country Settings Tab

Click *Country Settings* to open the window.

Note

After selecting the language, first load the factory settings to set all text libraries to the new language sets.



1 Language selection.

2 Time format.

3 Date format.

4 Select units for weight and height.

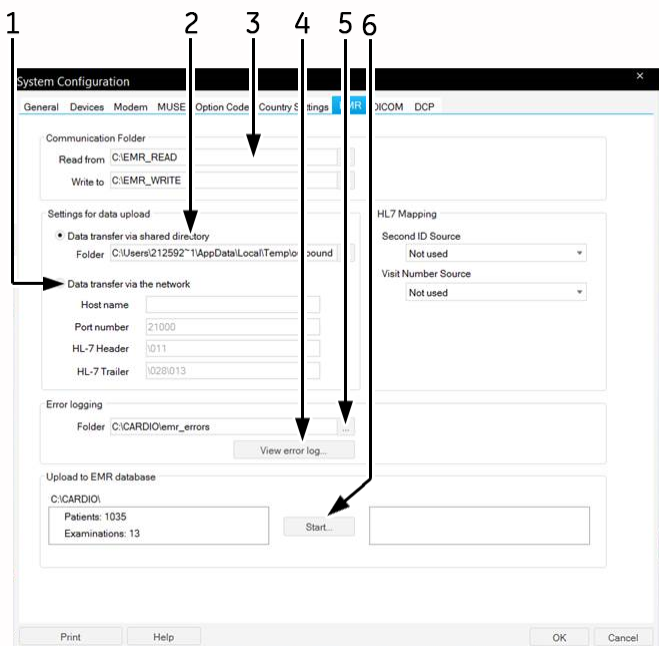
5 Treadmill speed unit selection. The speed unit must be match the treadmill's speed unit.

6 ST level unit.

7 AC line filter frequency.
8 ECG lead labels.
10 Atmospheric Pressure Unit for spirometry.
11 Blood pressure unit.
12 Cholesterol unit.
13 Display the patient's date of birth or age.
14 Enable the Swedish report formats.
15 Enable the Patient ID Check feature.
16 Set the Patient ID type.
17 Set the Patient ID length.
18 Enable Patient ID fill up.
19 Enable the race list on the patient information sceen.
20 Enable the Second ID.
21 Enable the visit number.

EMR Tab

Click *EMR* to open the window (with XEMR option only).



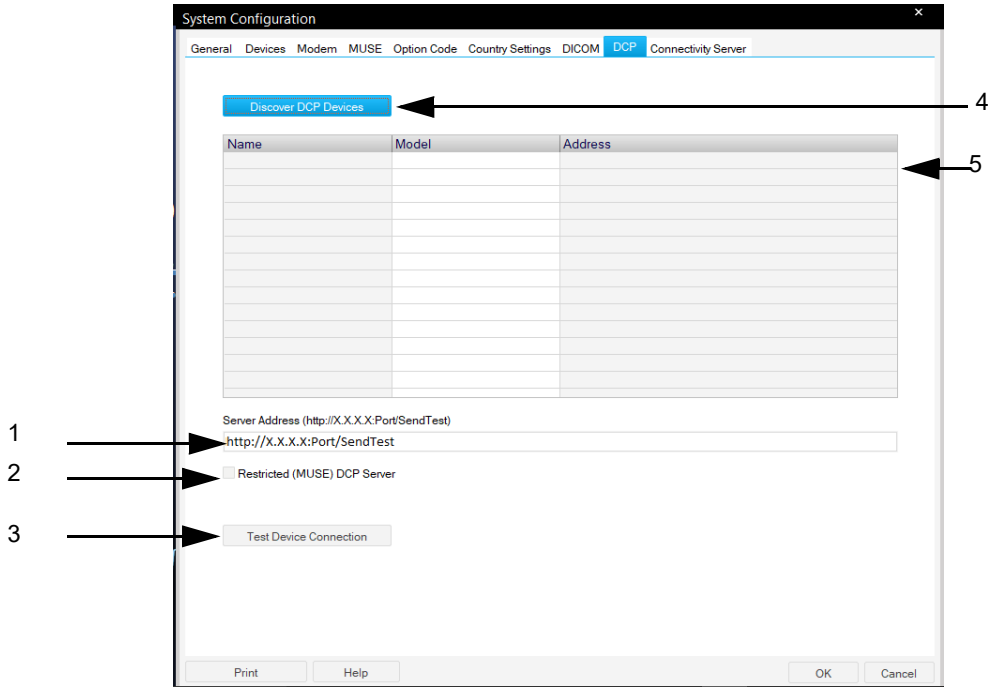
1 Transfer data to the EMR interface via a network.
2 Transfer data to the EMR interface via a shared directory.
3 Set or select the communication folders (read orders from the EMR interface, write data to the EMR interface).
4 View the error log.
5 Set or select the error log folder.
6 Start data transfer from CardioSoft to the EMR interface directories.

DCP Tab

Click *DCP* to open the window.

Note

To see the list of discovered servers and details, enter the server address and test the device connection. After successful device connection, the server details are populated.



1 Enter the IP address of the DCP server in the following format: http://<IP_Address>:Port/SendTest. The entered server address is serialized to the configuration file.

2 Select *Restricted (MUSE) DCP Server* if the DCP server is a MUSE server.

- If Restricted (MUSE) DCP server option is selected, then via DCP protocol, the system sends Resting ECG and Exercise test reports in Hilltop format to the MUSE server.
- If Restricted (MUSE) DCP server option is not selected, then via DCP protocol, the system sends:
  - Resting ECG and Exercise test reports in Hilltop and PDF formats to the DCP server. 12SL Analysis ECG tests recorded during an exercise test are sent as individual Resting ECG tests.
  - Spirometry and ABP test reports in Sapphire XML (containing only demographics) and PDF reports to the DCP server.

3 Test the device connection for DCP connectivity.

4 Click *Discover DCP Devices* to see the list of the discovered servers.

5 Lists the discovered DCP servers.

Connectivity Server Tab

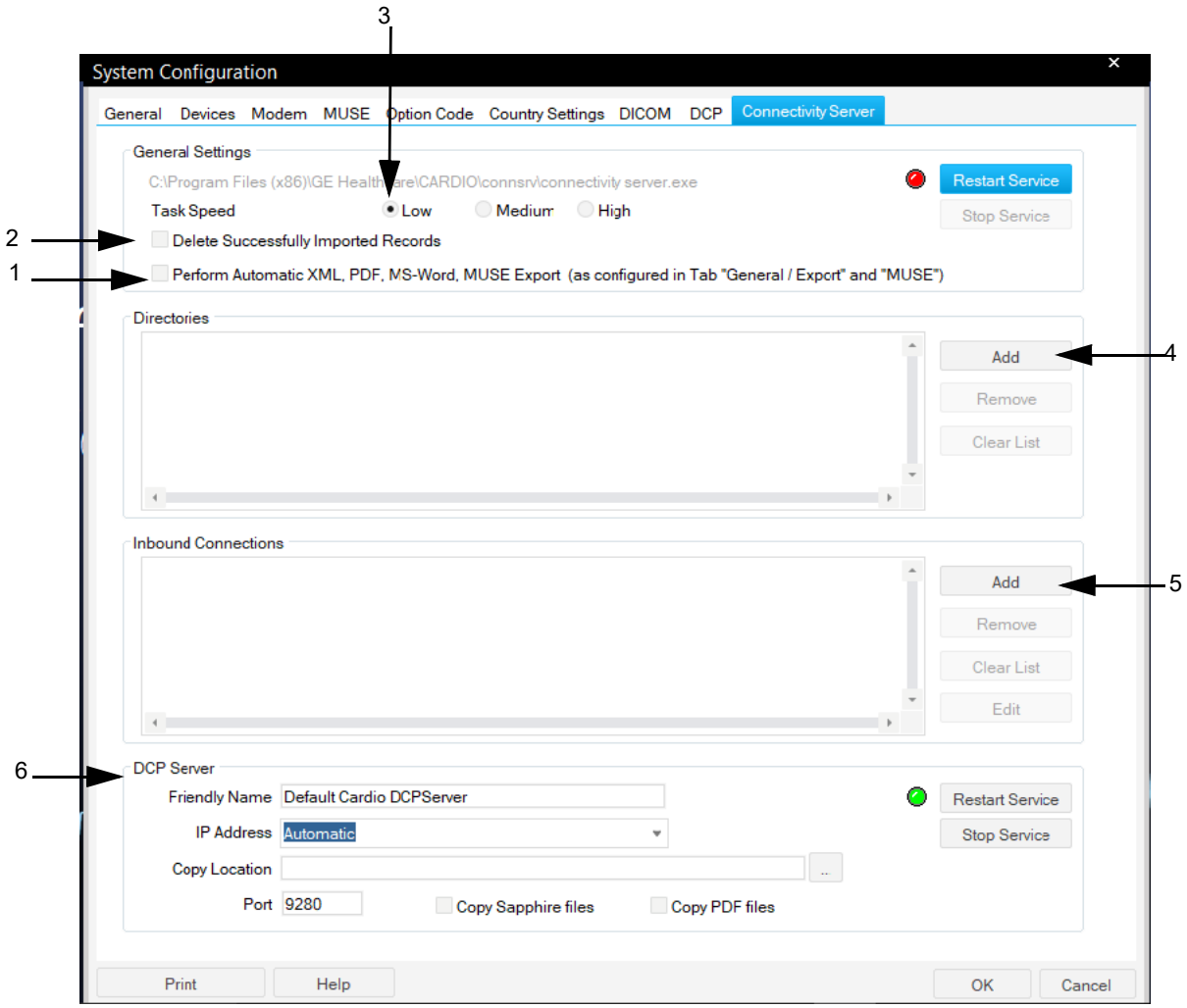
Note

Information about installing the connectivity server can be found in the CardioSoft Installation and Upgrade Guide. Refer the installation of the connectivity server to GE Healthcare service personnel.

Click *Connectivity Server* to open the window.

Note

Delete patient records that were successfully imported to the CardioSoft database from a remote folder.



1 Automatically export data in Word, XML or PDF format as configured in the System Configuration (see "System Configuration" on page 12-35 and "Exporting a Patient Record" on page 9-6). The selection is also valid for data export to the MUSE system (see "MUSE Tab" on page 12-44).
If deselected, the system settings defined for export and for MUSE apply.

2 Select check box to delete patient records that were successfully imported.

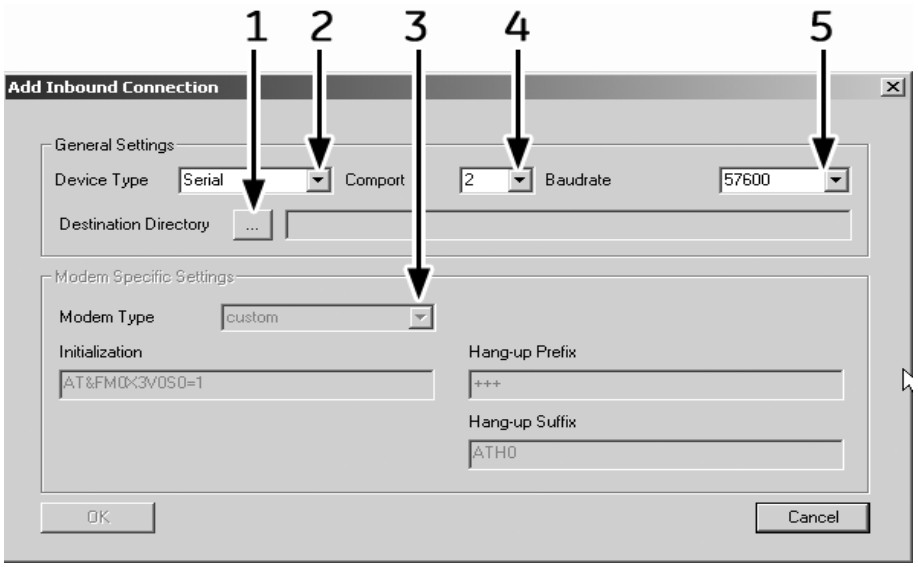
3 Query speed - Low: long pause between query cycles, High: short pause.

4 Open a dialog to add shared directories. You select a folder for which you have permission to save data. Normally, a user will be created and the rights needed to save data are assigned to this user. On the cart, this user is used to log onto the system.
After this, the folder is regularly checked and existing data records are transferred.

5 Open a dialog to add inbound connections.

6 Configure the connectivity server as a DCP server.

Add Inbound Connections Window



1 Select the target directory (the existing directory where the incoming data are stored will be added here). The connectivity server will monitor this directory and the data received will be downloaded.

2 Set connection: *Serial* or *Modem*.

3 Set the modem type (see "MUSE Tab" on page 12-44).

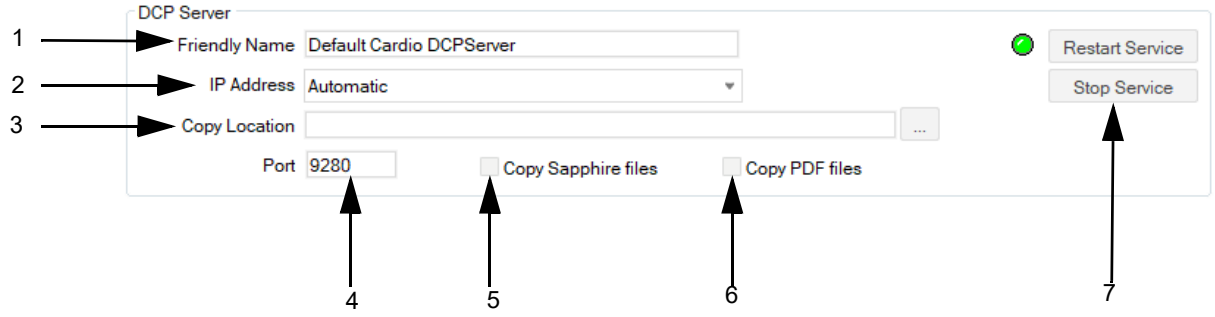
4 Port for the connectivity server. The server will receive data via this port (usually in conjunction with serial/IP software which provides virtual COM ports and is able to map TCP/IP (LAN) links to COM ports).

5 Baud rate. For modems, a maximum baud rate of 57600 is supported, for serial connections, a maximum baud rate of 115200.

Configure DCP Server

Note

Connectivity Server as DCP Server supports receiving Resting ECG data from a DCP client (MAC 800 and MAC 2000) in Hilltop format.



1 Enter the DCP server name.

2 Enter the IP address of the DCP network adaptor.

3 Configure a Copy Location to define a destination folder for the received files.

4 Enter DCP port number. The default value is 9280.

5 Select Copy Sapphire files to save received Sapphire XML files to the configured folder.

6 Select Copy PDF files to save received pdf files to the configured folder.

7 Restart or stop the DCP service.

DICOM Tab

Note

A valid DICOM option code will activate the DICOM interface as well as the *DICOM* tab.

Configurations on the *DICOM* tab should be referred to IT/Service staff (see Field Service Manual).

A Cleaning and Maintenance

For your notes

Equipment Cleaning, Disinfection, and Maintenance

Equipment Surface

Warning
SHOCK HAZARD — Disconnect the power cord from the wall outlet before cleaning or disinfecting the system.

- Use a moist cloth to wipe the surface clean; do not allow liquids to enter the system. All cleaning agents and disinfectants commonly used in hospitals and containing up to 70% alcohol are suitable. If liquids have entered the system, notify service to have the system inspected for damage before it is used again.
- DO NOT use disinfectants with a phenol base or peroxide compounds to disinfect the external surfaces.

Cleaning/Disinfecting

1. Remove all batteries and leadwires.
2. Close the battery door before cleaning the device.
3. Wipe the exterior of the device with a soft lint-free cloth, using the following solution as recommended in the APIC Guidelines for Selection and Use of Disinfectants:
   - Sodium hypochlorite (5.2% household bleach) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution.
   - Any sodium hypochlorite wipe product that meets the above guidelines of can be used.

Note
Wring excess disinfectant from wipe before using.

Note
Any contact of disinfectant solutions with metal parts may cause corrosion.

4. Allow disinfectant solutions to remain on device for a minimum of one minute or per hospital guidelines.
5. Wipe off cleaning solutions with a clean, moist cloth.
6. Dry thoroughly with a dry lint-free cloth and let air dry at least 30 minutes.

Note
Drying times may vary based on the environmental conditions.

7. Take care not to let fluid pool around connections pins. If this should happen, blot dry with a soft, lint-free cloth.

Cautions

- Never immerse the device in any liquid.
- Do not pour or spray any liquid directly on the device or permit fluid to seep into connections or openings.
- Never use conductive solutions, solutions that contain chloride, wax, or wax compounds to clean the device.
- Never use solutions or products that contain the following:
  - Any type of Ammonium Chloride such as, but not limited to:
    - Dimethyl Benzyl Ammonium Chloride
    - Quaternary Ammonium Chloride solutions
  - Abrasive cleaners or solvents of any kind
  - Acetone
  - Ketone
  - Betadine
  - Alcohol-based cleaning agents
  - Sodium salts
- Never autoclave or steam clean the device.
- Do not attach the device to a patient until it is thoroughly dry.

Storage

- Always remove batteries when the device is not in use (even for short periods of time).
- Store in a dry well-ventilated area.
- Hang the device, use a holder if available.
- If leadwires/cables are attached, they should hang straight.
- Do not coil leadwires/cables tightly around the device.

Improper Cleaning Products and Processes Impact/Results

- Appearance of waveforms when the device is not connected to a patient, causing false alarms instead of a leads fail alarm and may not provide a visual and/or audible leads fail alarm.
- Brittle and breaking device case.
- Overall system performance degradation.
- Melting, dulling, or distorting the case.
- Total handheld medical device failure requiring replacement.
- Unit malfunction.
- Void warranty.

Cleaning Products to Avoid

Cleaning products known to cause the types of problems listed above include, but are not limited to:

- Sani-Cloth® Wipes
- Ascepti® Wipes
- HB Quat®
- Clorox® Wipes (they do not contain bleach)
- Over-the-counter detergents (e.g Fantastic®, Tilex®, etc.).

Products that contain active ingredients and solutions similar to these products should also be avoided.

Maintenance

Before Each Use

Before each use, visually inspect the equipment, the cables and the electrodes for signs of mechanical damage.

If you detect damage or impaired functions which may result in a hazard to the patient or the operator, the items must be repaired or replaced before use.

The system does not require other regular maintenance.

Technical Inspections

For safety, the devices require regular maintenance. To ensure functional and operational safety of this system, Technical Inspections should be carried out on an annual basis.

These checks should be referred to individuals with adequate training and experience.

The inspections can be carried out by GE Healthcare Service within the framework of a service agreement. The Technical Inspections include:

- Visual inspection of the device and of the accessories for mechanical damage that may impair their function.
- Verification of the safety-related labeling for legibility.
- A function test.
- Measurement of the leakage current and of the resistance of the protective conductor according to local regulations.

The system does not require other regular maintenance.

Disposal at the End of Its Service Life



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

TrueFlow™ Sensor Cleaning, Maintenance, and Disposal

For information on TrueFlow Sensor maintenance, cleaning and disinfection, see Spiro-SP TrueFlow Sensor Instructions for Use.

CAM14 Maintenance, Cleaning and Disinfecting

For information on CAM14 maintenance, cleaning and disinfection, see Maintenance chapter of the CAM-14®/CAM-HD® Acquisition Modules Service Manual.

Wireless GEH-ECG 1200 Maintenance, Cleaning and Disinfecting

For information on Wireless GEH-ECG 1200 see Wireless GEH-ECG 1200 User Guide.

CardioSoft Console Maintenance, Cleaning and Disinfecting

For information on CardioSoft Console maintenance, cleaning and disinfection, see cleaning and disinfection chapter of the CardioSoft Console Operator's Manual.

CardioSoft Console Transformer Maintenance, Cleaning and Disinfecting

For information on CardioSoft Console Transformer maintenance, cleaning and disinfection, see cleaning and disinfection chapter of the CardioSoft Console Transformer Instructions for Use.

CC14 - Cleaning, Visual Inspection, and Disinfecting

Regular maintenance, irrespective of usage, is essential to ensure that the equipment functions when required.

See the documentation provided with your peripherals for additional maintenance procedures.

Other Cleaning and Disinfection Agents

The following products are compatible with the CC14 and may be used for cleaning and disinfection:

- Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes
- Ethanol (ethyl alcohol) 96% (v/v)
- Hydrogen Peroxide 20% (v/v)
- Sodium Hypochlorite (NaOCl) 5% solution)
- Isopropyl alcohol 70% (m/m)

Cleaning and Disinfecting Guidelines

Observe the following cleaning and disinfection guidelines.

- Follow cleaning instructions and observe hazards exactly as issued by GE Healthcare or other suppliers listed.
- Avoid exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion.
- Avoid exposure to highly alkaline conditions (pH > 11), as this can damage products (for example, aluminum parts).
- Never use conductive solutions or solutions that contain wax or wax compounds to clean the equipment.
- Do not immerse in any liquid as this may corrode metal contacts and affect signal quality.
- Do not allow fluid to pool around connection pins. If this happens, blot dry with a soft, lint-free cloth.
- Avoid contact with open vents, plugs, or connectors during the cleaning and disinfecting procedures.
- Never autoclave or steam-clean.
- Do not use until thoroughly dry.
- Do not use any of the following materials to clean, because their use may damage equipment surfaces.
  - Organic solvents
  - Abrasive cleaners or solvents of any kind
  - Acetone
  - Ketone
  - Betadine
  - Sodium salts

Visual Inspection, Cleaning, and Disinfecting Frequency

The following table indicates the frequency with which you should perform the visual inspection, cleaning, and disinfecting procedures.

Component	Visual Inspection	Cleaning	Disinfecting
Acquisition Module	Daily	After use on each patient and prior to use on subsequent patient.	After use on each patient and prior to use on subsequent patient. Disinfection must be performed after cleaning.

Visual Inspection

Inspect the Acquisition Module daily or if you suspect a problem. During the inspection, verify that the device meets the following minimum conditions:

- Check the leadwires and leadwire adapters for wear and loose connections. Replace these parts at the first sign of wear.
- Check the pins that the leadwires plug into. They should not be bent or loose. Contact GE Healthcare Customer Support for any repairs needed.
- Check the Acquisition Module plastic case for any damage. Contact GE Healthcare Customer Support for any repairs needed. Refer to supplier's instruction manual for detailed information.

Cleaning and Disinfecting the CC14 Acquisition Module

Proper cleaning and disinfecting prolongs the life of acquisition devices. Failure to use the proper cleaning solutions or to follow proper procedures can result in the following:

- Appearance of waveforms when not connected to a patient, resulting in false alarms instead of lead failure alarms
- Brittle and cracked device case
- Melting, dulling, or distortion of the case
- Total device failure, requiring replacement
- Unit malfunction
- Voided warranty

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Cleaning the Acquisition Module

1. Dispense Super Sani-Cloth® Wipe(s) from the canister.
2. If soil is present, thoroughly wipe the surfaces of the device with a fresh Super Sani-Cloth Wipe for a minimum of two minutes and until soil and organic matter have been visibly removed.

   Treated surfaces must remain visibly wet for a minimum of two minutes. Use additional fresh disinfectant wipes, if needed, to ensure continuous two minutes contact time. Pay attention to the recessed areas and ridges; use a cotton swab to press onto the wipe for scrubbing these areas.
3. Inspect the device and trolley to ensure the complete removal of soil from surfaces, holes, and movable parts.

   If soil is still present, re-clean the equipment by repeating step “2”.
4. Allow the device to air dry.
5. Discard wipes to clinical waste. Do not reuse wipes.

Post-Cleaning Inspection

GE Healthcare devices should be visually inspected and functionally tested after cleaning and prior to disinfection for the following items:

- Cleanliness.
- Damage, including but not limited to corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear.
- Missing or worn part numbers.
- Proper functioning, including but not limited to the quality of ECGs;

  correct movement of hinges, joints, box locks, handles, ratchets, and couplings; proper alignment of jaws and teeth; and secure fastening of all locking mechanisms.

Do not use devices that are not functioning properly, that have unrecognizable markings, that have missing or worn part numbers, or that are damaged. Disassembled devices should be reassembled prior to disinfection unless otherwise instructed.

Disinfecting the Acquisition Module

Ensure that thorough cleaning is performed to remove all visible soil and organic matter prior to disinfection.

1. Dispense fresh Super Sani-Cloth® Wipe(s) from the canister.
2. Apply disinfectant to the entire surface using fresh wipes.

   Treated surfaces must remain visibly wet for a minimum of three minutes. Use additional fresh disinfectant wipes, if needed, to ensure continuous three minutes of contact time. Pay attention to the recessed areas and ridges; use a cotton swab to press onto the wipe to moisten these areas.
3. Remove disinfectant residue from the device by thoroughly wiping surfaces with a disposable, lint-free wipe moistened with 70% Isopropyl Alcohol (IPA) solution.
4. Allow the device to air dry.
5. Discard wipes to clinical waste. Do not reuse wipes.

Cables and Electrodes Cleaning

- Disconnect the cable from the system before cleaning or disinfection. To disconnect cables, always pull on the plug, not on the cable.
- Discard single-use adhesive electrodes immediately after removing them from the patient to prevent that they are reused.

Caution
IMPROPER FUNCTIONING — Lead wires and electrodes that are not functioning properly could result in ECG distortion or failure.

Carefully inspect instruments between uses to verify proper functioning

Refer to the supplier's instructions for leadwire and cable cleaning and disinfection.

Refer to the supplier's instructions for reusable electrode cleaning, disinfection, and sterilization.

See the *Diagnostic Cardiology Supplies and Accessories Guide, 2102946-001*.

Tonoport

For information on Tonoport maintenance, cleaning and disinfection, see Cleaning, Maintenance, Disposal chapter of the TONOPORT Operator's Manual.

B Miscellaneous

For your notes

Connecting Peripheral Devices

Note
Peripheral devices must be calibrated before being used with the system. Refer to the appropriate service manuals for calibration information.

Bicycle Ergometers

Connect bicycle ergometers to the Serial port or USB.

Model	Configuration
eBike basic, eBike comfort, eBike L, eBike EL	eBike

Set the following parameters at the ergometer:

- ECG type: P10
- Baud rate: 4800

The ergometer software must be version V436 or V236; ergometers with a 4-button control panel must be software version 752 or M343.

Plug the round connector of the connecting cable into the J10/RS 232 port of the ergometer and the other end into one of the Serial port or USB of the system.

Treadmills

Connect treadmills to the Serial port or USB.

Model	Configuration
Treadmills without digital communication interface	Internal treadmill
■ T2100-ST1 and T2100-ST2	
■ T2100	T2100

Note
Other bicycle ergometers and treadmill models with an analog port can be connected to the analog output of the system.

Blood Pressure Monitor

Note
The blood pressure can be measured in kPa or mmHg. For selection of the blood pressure unit, see "Country Settings Tab" on page 12-46.

Connect blood pressure monitors to the Serial port or USB.

Model	Configuration
Integrated in the ergometer	Integrated in the ergometer
No BP monitor (with prompt to take BP measurement)	None
SunTech Tango M2, Tango+	SunTech

The BP monitor must be ready for operation before the exercise test is activated. Otherwise the system will not recognize it and prompt the user to take manual BP measurements.

If a measurement takes more than 60 seconds to complete, the values may appear in the tabular data for the next stage or phase.

If no external BP monitor is connected, the system defaults to the BP monitor integrated in or connected to the ergometer.

Note

Always use the SunTech ECG electrodes, when taking BP measurements with the SunTech during exercise tests.

Setting Up the SunTech BP Monitor

This BP monitor needs to be configured one time,

1. On the program screen select *Change Test Parameters*.

   Move the cursor with the *LAST* and *NEXT* keys.

2. Confirm selections with *YES*.
3. Select *Set BP Reading Interval* and press *YES* to confirm the selection.
4. Select *MAN* for *PRE*, *TEST* and *POST* (with *YES* or *NO*, 1 to 90 min, *MAN*).
5. Display the program screen again by pressing *OK* twice and select *Utilities*.
6. Confirm the selection with *YES*.
7. Choose *Select System Interface* and press *YES* to confirm the selection.
8. Select *SUNTECH* with *YES* or *NO*.
9. Display the program screen again by pressing *OK* twice.

The setup is now complete. The system will start the BP monitor.

SpO_2 Monitor

Connect SpO_2 monitors to the Serial port or USB.

Model	Configuration
SunTech Tango+ with SpO_2 option and Tango M2	in BP monitor

The system only indicates the current SpO_2 level.

Configurations are performed directly at the SpO_2 monitor.

ECG Recorder

Connect MAC 600, MAC 800, MAC 1600, MAC2000, MAC 3500, MAC 5000, MAC 5500 to LAN, AND serial port (RS232).

Modem

Connect the modem to a Serial port or USB.

Laser Printer

Note

For printer selection information, see "System Settings" on page 12-1.

Printers in a Network Environment

Warning

PATIENT HAZARD — As stipulated in IEC 60601-1, printers operated in the patient environment must be connected via an isolation transformer or to a potential equalization system (protective earth conductor).

- Recommended storage capacity: 8 MB
- Recommended printer: HP LaserJet P3015dn.

Caution

The ambient conditions for the CardioSoft system are different to those of most laser printers. Ensure ambient conditions suitable for the laser printer.

Application Tips

General Application

When operating the system in a network environment, periodically scan the system for viruses. The anti-virus software should be updated on a weekly basis. Customers are responsible for installation and maintenance of anti-virus software.

Recording ECGs of Pacemaker Patients

It is not possible to display pacing pulses directly in all situations. At a sweep speed or writer speed of 50 mm/s and a pulse duration of just 0.5 ms, the width of the recorded pacing pulse would be a mere 0.025 mm. When the pace enhancement is enabled (see "Miscellaneous Tab" on page 12-22), a 6-ms impulse with the correct polarity and with an amplitude of 0.5 mV replaces the pacer pulse. Depending on the polarity of the pacer pulse in leads I and II, the pacer pulse in lead III may be suppressed.

Note

- The ADS and the FRF algorithm cause a signal delay of approximately one second; therefore they should be disabled for adjustment of the pacemaker parameters.
- If several adverse conditions exist at once, the possibility of pacer pulses being interpreted as QRS complexes should be considered. At the same time, however, QRS complexes might be suppressed in certain situations. For safety, always watch pacemaker patients closely.

Recording ECGs During Defibrillation

The patient signal input is defibrillation-proof. Therefore, it is not necessary to remove the ECG electrodes prior to defibrillation.

When using stainless steel or silver electrodes a defibrillator discharge current may cause the electrodes to retain a residual charge causing a polarization or DC offset voltage at the electrode/skin interface. This electrode polarization will block acquisition of the ECG signal for several minutes. To avoid this condition, use silver-silver chloride electrodes.

If other electrodes are used, we recommend disconnecting the patient cable from the system before delivering the defibrillation shock.

The ADS and the FRF algorithm cause a signal delay of approximately 1 second (ADS) and 1.5 seconds (FRF) respectively; therefore they should be disabled if the patient has to be defibrillated while the ECG is being recorded ("Acquisition Tab" on page 12-20).

Note

If excessive DC voltages are present at the electrode, then a message will appear indicating a Lead Off condition.

Exercise Test Interpretation (XTI)

An exercise test on a treadmill or a bicycle delivers a large number of measurements that are valuable in predicting morbidity/mortality, in detecting coronary artery disease and in describing the functional exercise response of a patient.

However, it is very difficult to have a comprehensive knowledge of all measurements and their thresholds, especially of the new ones, namely HR recovery, FVE recovery, ST/HR hysteresis, and HR reserve used.

The Exercise Test Interpretation (XTI) program compares the exercise measurements against established thresholds and provides statements and reasoning text (explanation of the statements) when thresholds are exceeded.

Following is an example of a statement with the accompanying reasoning text:

Ischemia, probably caused by coronary artery disease

because ST/HR hysteresis > 0.02 mV in [V5 V6] and

HR reserve used < 70%

The intention of the statements and reasoning text is to provide a short, clear, and accurate overview of the results of an exercise test.

For more details, see Physician's Guide to GE Stress Systems, Part No. 2051167-002.

Duke Treadmill Score

1. The system automatically generates the Duke Treadmill Score using the following standard computation.

$$\text{Duke Treadmill Score} = \text{(Bruce) Exercise Time (minutes)} - 5 \left\{ \text{maximum ST deviation (mm)} \right\} - 4\,(\text{Angina Index})$$

Angina-Index 0 = none, 1 = non-limiting, 2 = limiting

HINWEIS

Maximum ST deviation refers to the amount of exercise-induced ST segment deviation, i.e., the largest elevation or depression after baseline ST levels have been subtracted.

- The calculated ST deviation value depends on the J+x setting (default: J+60 ms). High heart rates may affect the accuracy of this value.
- The calculated ST deviation does not differentiate between horizontal, down sloping and up sloping ST segments, nor is Q wave significance considered.

HINWEIS

The user must verify and possibly correct the system-calculated value.

2. Duke Treadmill Score Risk Categories are assigned according to the following ranges:
   - ≥ (+5) low
   - (-10 to +4.9)intermediate
   - < (-10) high
3. Prognosis percentages for five-year survival and average annual mortality are calculated from the nomogram of the prognostic relations embodied in the Duke Treadmill Score.
4. Exercise time using the Bruce Protocol is standard. Equivalent measures in multiples of resting oxygen consumption (METS) from an alternative protocol can be used.

References

Study the following publications for a correct understanding of the Duke Treadmill Score:

Gibbons et al.: ACC/AHA Guidelines For Exercise Testing. JACC, 30 (1):260 - 315, July 1997.

Mark, D.B.; Shaw, L.; Harrell, F. E.; Lee, K. L.; Bengton, J.R.; McCants, C.B.; Califf, R.M.; Pryor, D.B.: Prognostic value of a

treadmill exercise score in outpatients with suspected coronary artery disease. The New England Journal of Medicine. 325 (12): 849 - 853 (Sept. 1991).

Mark, D.B. An overview of risk assessment in coronary artery disease. The American Journal of Cardiology. 73: 19B - 25B (March 1994).

Mark, D.B.; Hatky, M.A.; Harrell, F.E.; Lee, K.L.; Bengton, J.R.; Califf, R.M.; Pryor, D.B. Exercise treadmill score for predicting prognosis in coronary artery disease. Annals of Internal Medicine. 106 (6): 793 - 800 (June 1987).

Risk Factors

According to the "Instructions of Using Coronary Risk and Stroke Risk Prediction Charts and Worksheet" proposed by the American Heart Association (AHA) (see also Physician' s Guide to GE Stress Systems) the system automatically calculates the risk factors for coronary heart disease and myocardial infarction. If an input value is unknown or out-of-range, the system uses the following risk factor values:

Table 4. Coronary Heart Disease Risk Factor Values for Unknown or Out-of range Parameters

Parameter	Value	Value Used
Age (female) unknown	unknown	40
	< 30 years	30
	> 74 years	74
Age (male) unknown	unknown	33
	< 30 years	30
	> 74 years	74
Age (gender unknown)	all values	33
HDL-Cholesterol	unknown	50
	< 25	25
	> 96	96
Total-Cholesterol	unknown	199
	< 139	139
	> 330	330
Systolic Blood Pressure	unknown	120
	< 98	98
	> 185	185
Smoker	unknown	no
Diabetic (male or female)	unknown	no
Diabetic (gender unknown)	all values	no
ECG-LVH (ECG indicative of left-ventricular hypertrophy)	unknown	no

Table 5. Male Stroke Risk Factor Values for Unknown or Out-of range Parameters

Parameter	Value	Value Used
Age	unknown	56
	< 54 years	54
	> 86 years	86
Systolic Blood Pressure	unknown	105
	< 95	95
	> 213	213
HYP RX (anti-hypertensive medication)	unknown	no
Diabetes	unknown	no
Smoker (cigarettes)	unknown	no
CVD (cardiovascular disease)	unknown	no
AF (atrial fibrillation)	unknown	no
LVH (left-ventricular hypertrophy)	unknown	no

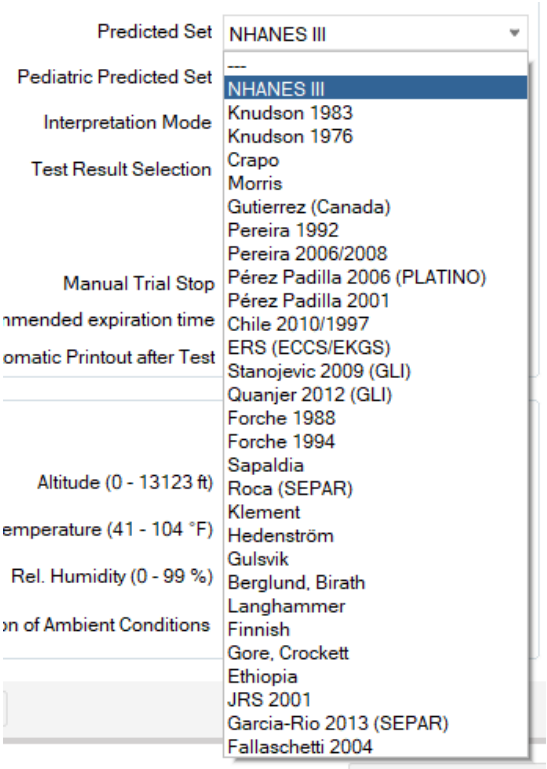
Table 6. Female Stroke Risk Factor Values for Unknown or Out-of range Parameters

Parameter	Value	Value Used
Age	unknown	56
	< 54 years	54
	> 86 years	86
Systolic Blood Pressure	unknown	104
	< 95	95
	> 204	204
HYP RX (anti-hypertensive medication)	unknown	no
Diabetes	unknown	no
Smoker (cigarettes)	unknown	no
CVD	unknown	no
AF	unknown	no
LVH	unknown	no

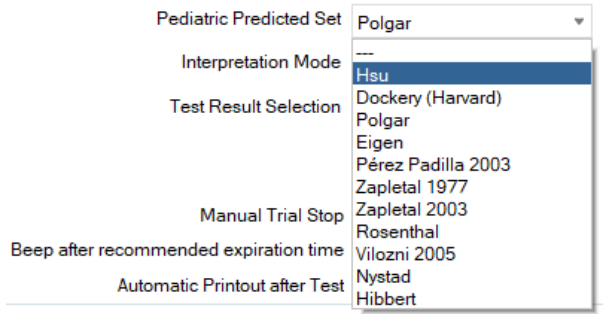
Spirometry Reference Value Equations, Interpretation Modes, Measurements

Reference Value Equations

The following figure displays the supported referenace value for predicted set.



The following figure displays the supported referenace value for pediatric predicted set.



Interpretation Modes

Note

The authors of the reference values developed the interpretation modes for the reference value equations. Other reference value equations may lead to different interpretations.

Europe

An interpretation mode on the basis of the ECCS reference values. The flow-volume loop is analyzed according to these criteria:

1. Expiratory flow limitation?
2. Curve typical of restriction?
3. Expiratory stenoses?
4. Impaired peripheral respiration?

Expiratory flow limitation

Possible causes	increased airway resistance (for example, asthma), reduced pulmonary elasticity (for example, emphysema), airway obstruction
Criterion	**MEF50 % VC Ref.**
Definition	**Interpretative Statement**
> 70 %	normal*
50 ... 70 %	mild expiratory flow limitation
35 ... 49 %	moderate expiratory flow limitation
< 35 %	severe expiratory flow limitation
if < 70 %	further lung function measurement recommended

* If all four interpretation criteria are *normal*, the interpretative statement *Normal lung function values* is displayed.

Curve typical of restriction

Possible causes	reduced lung volume (restriction), elevated pulmonary elasticity (fibrosis)
Criterion	**FVC Act. < xx % FVC Ref. and (VC MAX/(2 x MEF50) < 0.8)**
Definition	**Interpretative Statement**
> 70 %	normal*
50 ... 70 %	curve typical of mild restriction
< 49 %	curve typical of moderate to severe restriction
if < 70 %	further lung function measurement recommended

Expiratory stenoses

Possible causes	Stenoses in the large airways, extrathoracic flow obstruction, expiratory tracheal stenosis
Criterion	**FVC Act./PEF > 0.8**
Definition	**Interpretative Statement**
< 0,8	normal*
> 0,8	Further examination for extrathoracic flow obstruction and expiratory tracheal stenosis recommended. Watch patient cooperation.

* If all four interpretation criteria are *normal*, the interpretative statement *Normal lung function values* is displayed.

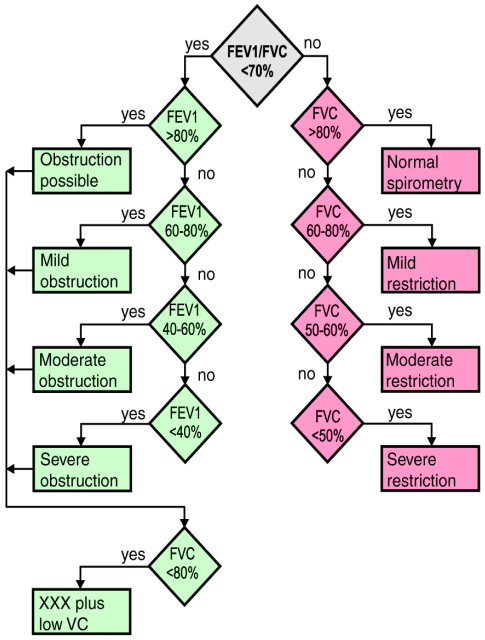
Impaired peripheral respiration

Possible causes	reduced pulmonary elasticity (emphysema), impaired ventilatory distribution, peripheral airway obstruction
Criterion	**VC MAX/(2 x MEF50)**
Definition	**Interpretative Statement**
T50 % = < 0.8 s	normal*
T50 % = 0.8 - 1 s	mild expiratory flow limitation at deep expiration
T50 % = > 1 s	moderate to severe expiratory flow limitation at deep expiration
if > 0.8 s	further lung function measurement recommended

* If all four interpretation criteria are *normal*, the interpretative statement *Normal lung function values* is displayed.

CHS

Interpretation mode based on the "American Thoracic Society recommendations for disability testing." The most important criterion used is the FEV1/FVC ratio; the changes of FEV 1 and FVC are also considered. The underlying reference values are those published by KNUDSON.



211A

XXX = "Obstruction possible" or "Mild" or "Moderate" or "Severe obstruction"

System Interpretation

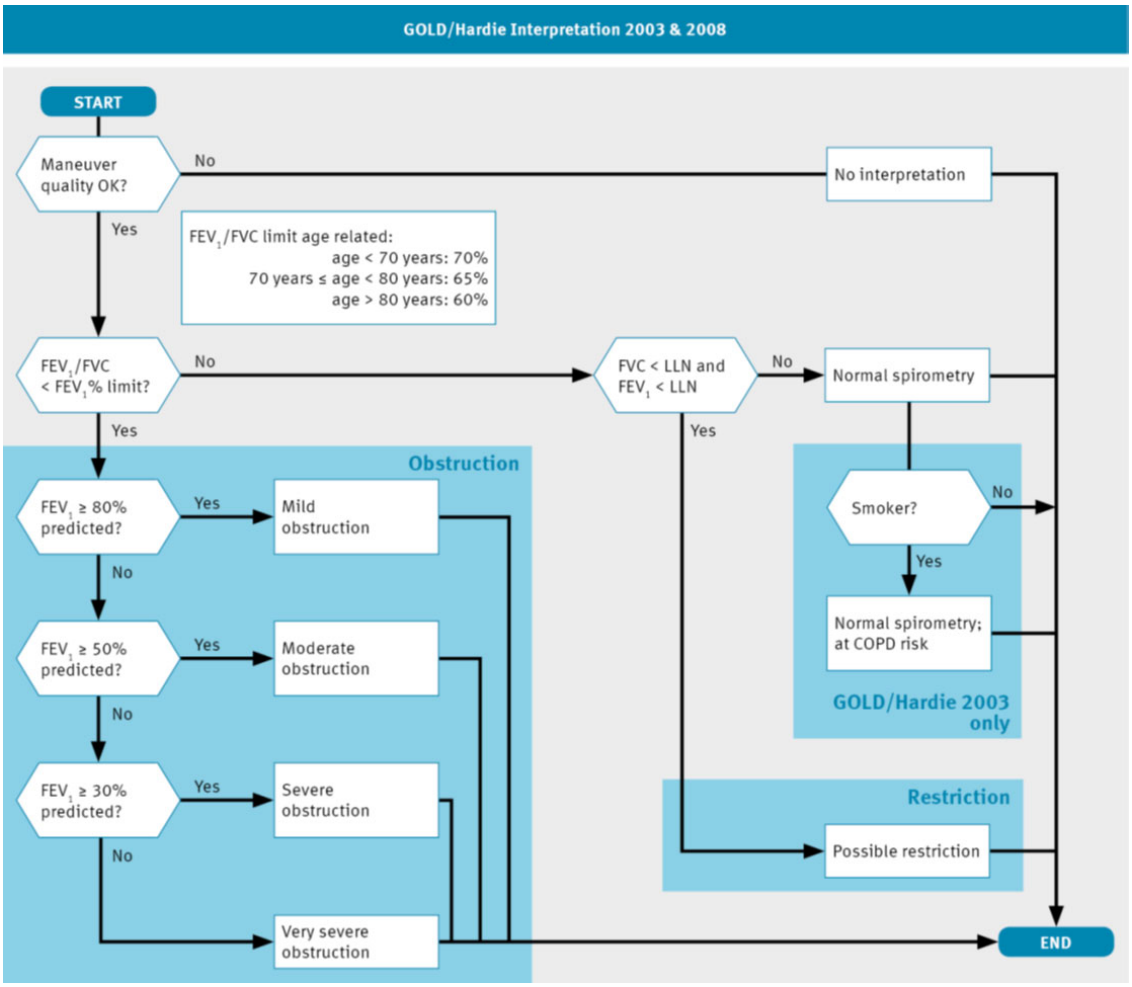
Following are the automatic system interpretation that can be selected in the setup for Spirometry tab.

- GOLD-Hardie Interpretation 2003/2008
- NLHEP Interpretation
- NICE Interpretation

GOLD-Hardie Interpretation 2003/2008

Following diagram outlines the criteria according to GOLD/HARDIE:

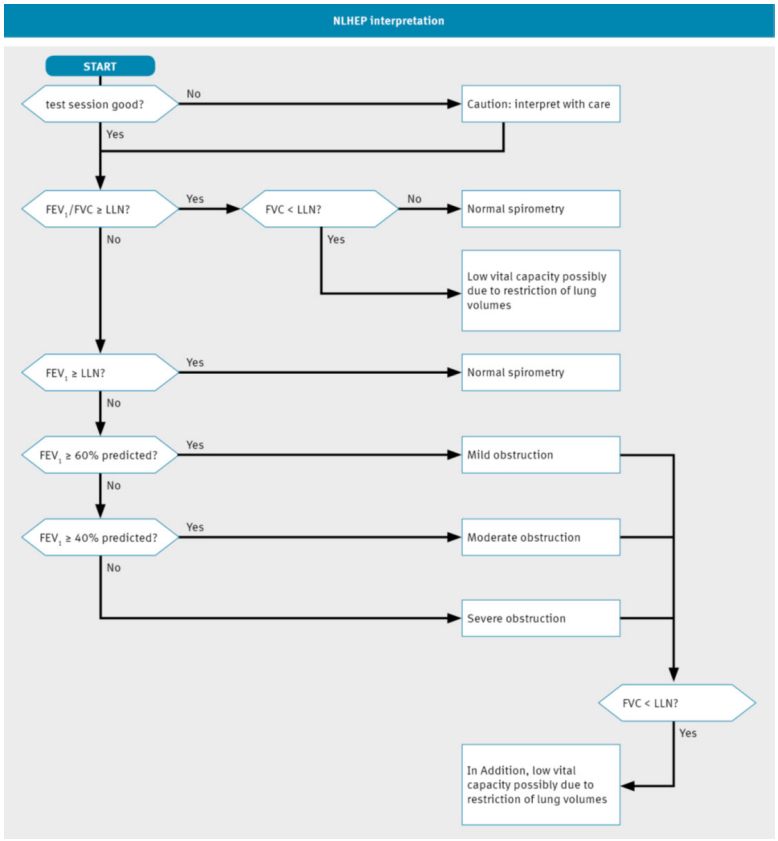
- GOLD 2003 and 2008: Global Strategy for Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease, Executive Summary. Update 2003 and Update 2008
- GOLD/HARDIE 2003 and 2008: Modified GOLD 2003 and 2008, Hardie et. al., “Risk of over-diagnosis of COPD in asymptomatic elderly never-smokers” Eur Respir J2002; 20:1117-1122



NLHEP Interpretation

Following diagram outlines the criteria according to NLHEP:

NLHEP: Ferguson GT, Enright PL, Buist AS, et al. Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program. Chest 2000; 117:1146-1161



Note

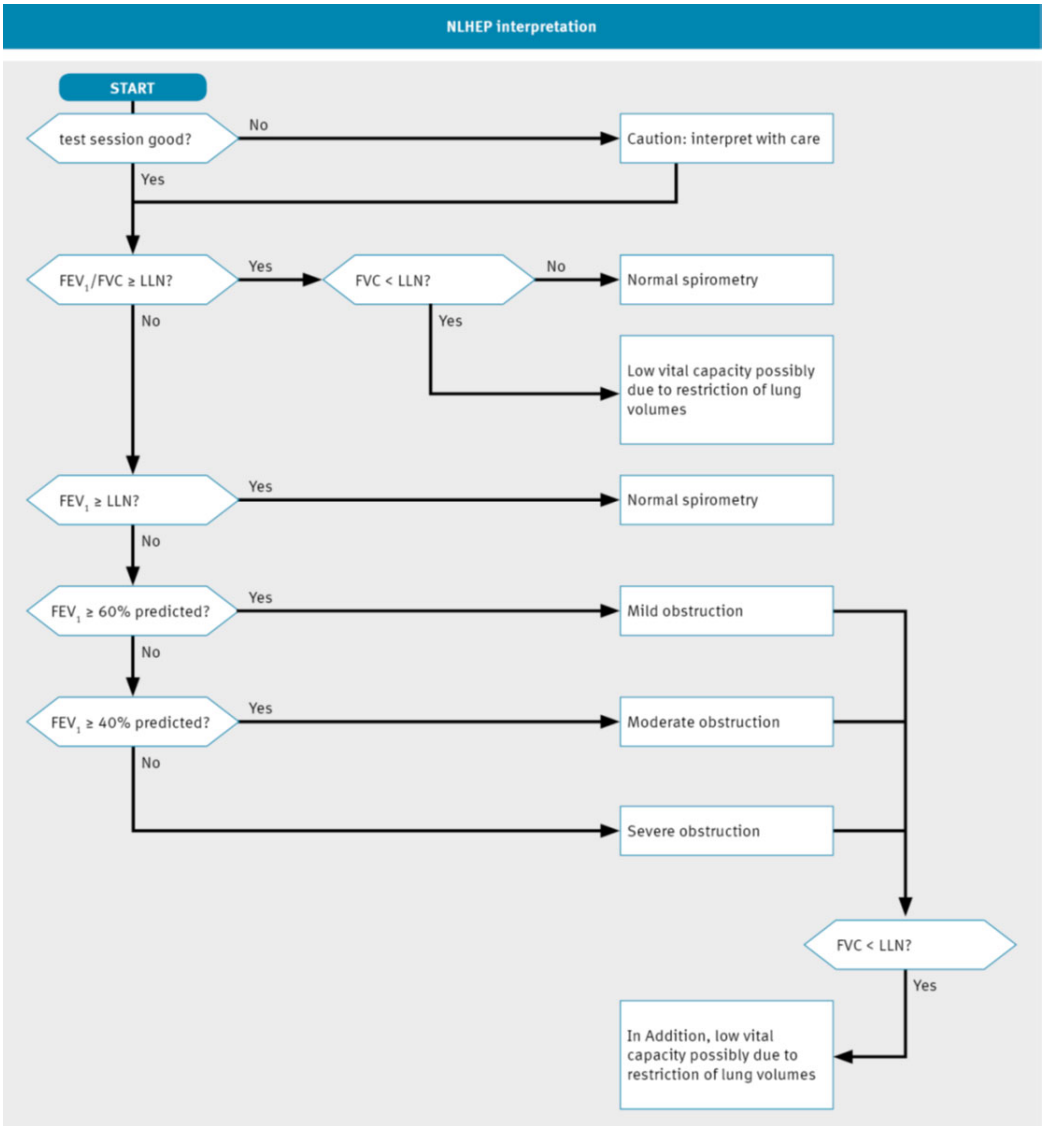
- LLN = Lower limit of normal
- If FEV6 is selected instead of FVC, FEV6 will be used for the interpretation instead of FVC.
- If the selected predicted set does not provide a lower limit of normal (LLN), LLN is calculated as predicted value - 1.645 x RSD (residual standard deviation). If RSD is not defined, the LLN for FEV1/FVC is set at 90% of the predicted value, the LLN for FEV1 at 80% of the predicted value and the LLN for FVC at 80% of the predicted value.
- If the quality grade is D and the results are within the limits, the interpretation will be: “Caution: Poor session quality. Interpret with care. Normal spirometry. Reported values should not be used for comparison with other tests”.

NICE Interpretation

Following diagram outlines the criteria according to NICE/ NICE 2010 applied in the automatic system interpretation.

"NICE: National Institute for Health and Clinical Excellence, Clinical Guideline 12 (2004)

"NICE 2010: National Institute for Health and Clinical Excellence, Clinical Guideline 101 (2010)


NLHEP interpretation
START
test session good?
No
Caution: interpret with care
Yes
FEV1/FVC ≥ LLN?
Yes
FVC < LLN?
No
Normal spirometry
No
Yes
Low vital capacity possibly due to restriction of lung volumes
FEV1 ≥ LLN?
Yes
Normal spirometry
No
FEV1 ≥ 60% predicted?
Yes
Mild obstruction
No
FEV1 ≥ 40% predicted?
Yes
Moderate obstruction
No
Severe obstruction
FVC < LLN?
Yes
In Addition, low vital capacity possibly due to restriction of lung volumes

Definition of Spirometry Test Values

FVC	forced expiratory vital capacity
FEV05	forced expiratory volume in the first 0.5 seconds
FEV1	forced expiratory volume in the first second (same as FVC, if exhalation time < 1 second)
FEV1/FVC	FEV1 as a percentage of FVC
FEV1/VCmax	FEV1 as a percentage of VCmax
FEV3	forced expiratory volume in the first 3 seconds (same as FVC, if exhalation time < 3 seconds)
FEV6	forced expiratory volume in the first 6 seconds (same as FVC, if exhalation time < 6 seconds)
FEV1/FEV6	FEV1 as a percentage of FEV6
PEF	peak expiratory flow
MEF75 (FEF 25)	maximal expiratory flow when 75% of FVC remain to be exhaled
MEF50 (FEF50)	maximal expiratory flow when 50% of FVC remain to be exhaled
MEF25 (FEF75)	maximal expiratory flow when 25% of FVC remain to be exhaled
MMEF	maximal mid-expiratory flow (between 25 and 75% of FVC)
FIVC	forced inspiratory vital capacity
FIV1	forced inspiratory volume in the first second
FIV1/FVC	FIV1 as a percentage of FVC
PIF	peak inspiratory flow
MIF25	maximal inspiratory flow when 25% of FIVC have been inhaled
MIF50	maximal inspiratory flow when 50% of FIVC have been inhaled
MIF75	maximal inspiratory flow when 75% of FIVC have been inhaled
MVV(ind)	maximal expiratory ventilation volume in one minute (indirectly determined: 30*FEV1)
FET	Forced expiratory time
BEV	back extrapolated volume

VT.....Tidal Volume

IRV.....Expiratory reserve volume

VC or VCmax....Maximum vital capacity of a slow spirometry test

VCex.....Expiratory vital capacity of a slow spirometry test

VCin,,,,,,,,,,,,Insipratory vital capacity of a slow spirometry test

IC.....Inspiratory capacity

MVV.....Maximum voluntary ventilation

% Chg (PRE/POST%).....percentage deviation of the pre and post medication values (bronchodilation test)

CardioSoft Web

Retrieve tests via the Internet for display on any computer with CardioSoft web.

Note

For CardioSoft Web installation instructions, see the *CardioSoft Software Installation and Upgrade Guide*.

Points to Note

General	The ECG traces are superimposed on a grid pattern that neither adapts to the monitor size nor to the display resolution. The grid is designed for a 17-inch monitor with a resolution of 1024 x 768 pixels.
Exercise Tests	ST/HR Slope is not shown.
Spirometry Tests	The comparison of two spirometry tests is not shown.
Patient Administration	Archived patient records do not appear in the patient record list. The patient record list informs about test type date and time cart/device number confirmed (yes/no) transferred (yes/no) The patient list only indicates last name, first name, date of birth, and patient ID.

Displaying Tests

1. Enter the patient last name, or the first letter of the name (for example, click S to find the patient name Smith), and click *Find*.
2. The patient list displays.
3. Select the patient.

   The list of records for that patient displays.
5. Select a patient record to review.

Installing the Program in a Network Environment

Contact our Customer Service for program updates.

To operate the program in a network environment, the server must meet the following requirements:

processor	Pentium $\geq$ 1.6 GHz
RAM	$\geq$ 256 MB
hard drive	> 40 GB
operating system	Windows Server 2012, Windows Server 2012 R2, and Windows Server 2016
protocol	TCP/IP
cabling	twisted pair

Troubleshooting

Problem	Remedy
Installation of acquisition module not possible, module has problems sending data, red bar on ECG	**CAM-USB or CAM-USB A/T:** ■ green LED ON, yellow LED OFF: signal transmission in progress ■ green LED ON, yellow LED ON: ready to send ECG signals (for example, no communication with CAM14) ■ green LED OFF, yellow LED OFF: no power ■ green LED ON, yellow LED blinking: communication with CAM14 interrupted (for example, CAM14 not connected ■ When a communication problem between the CAM-USB interface box and the PC occurs (due to a program crash), the box will emit a continuous tone and both LEDs will be ON. ■ If the installed manufacturer's printer driver has a spooler or print status indicator (for example, HP), this driver must be uninstalled and all pertinent entries must be removed from the registry, if applicable. This should be referred to an authorized system administrator, because incorrect entries in the registry may cause the system to break down. Install a standard printer driver, for example, the Windows driver HP LaserJet 4 for laser printers.
Send exercise test data not possible	■ Check network address of the remote PC on your local PC and correct, if necessary. ■ Check option code and correct, if necessary. ■ Enable the *Remote View* function.
Exercise test analysis does not start	■ Not all required electrodes are applied. If you wish to initiate the analysis all the same, click the *Relearn medians* button.
Incorrect heart rate or arrhythmia results	■ The program may have selected two unsuitable leads. Manually select two good leads (see section "Miscellaneous Tab" on page 12-22).
Displayed data are incomplete.	■ The screen diagonal entered in the System Configuration (section "General Tab" on page 12-35) is incorrect. ■ For screens below 17 inches: the Windows taskbar is always on top (Windows settings - Taskbar). ■ Wrong screen resolution in Windows. Use *Small Fonts*.
System does not identify ergometer.	■ Incorrect ergometer model/port selected (section "Devices Tab" on page 12-42). ■ Check connection cable and connectors. ■ Turn ergometer off and on again. Restart CardioSoft.
No communication with MUSE.	■ Incorrect network address of the MUSE server or shared directory (section "MUSE Tab" on page 12-44). ■ Required options *Request MUSE Data* or *Send Data to MUSE* not enabled (section "MUSE Tab" on page 12-44). ■ Incorrect network configuration (system administrator). ■ Incorrect Internet Explorer setup (version >4.0 is required, also for sending data to MUSE).

Problem	Remedy
USB drive not found.	■ Restart system.
The ECG grid is not visible in the PDF file.	■ Set up Acrobat Distiller as follows Acrobat V6.0: ■ *Start -> Settings -> Printer -> Adobe PDF ->* menu *Printer -> Document Defaults ->* menu *Adobe PDF Settings ->* disable *do not send fonts to distiller*; menu *Paper/Quality ->* button *Advanced -> Graphic* and select the field *Download True Type Font as Softfont*. Acrobat V5.0: ■ *Start -> Settings -> Printer -> Acrobat Distiller ->* menu *Printer -> Document Defaults ->* menu *Adobe PDF Settings ->* disable *do not send fonts to distiller*; menu *Paper/Quality ->* button *Advanced -> Graphic* and select the field *Download True Type Font as Softfont*. ■ If these steps do not correct the problem, change the grid format: *System Configuration -> General* tab *-> Printer ->* deselect *Dotted line ->* select grid format. Tip: If the grid lines appear too strong, select a shade of gray rather than black.
Message Not enough free memory on hard drive!	■ Free storage capacity on the hard drive where your database is stored, for example, by compressing exercise test data or by deleting examinations. Also ensure that there is enough free storage capacity on the hard drive where your operating system is located and in the temporary directories (100 MB minimum).
After connection of the CAM-USB interface box to the PC, no ECGs are displayed	■ Remove connector of the CAM-USB interface box from the PC, wait about 10 seconds, then reconnect. When prompted to install a new USB device, clear the prompt or any other message with *Cancel*.
After connecting the Wireless GEH-ECG 1200WR Receiver to the PC, no ECGs are displayed.	■ Check if the GEH-ECG 1200 acquisition module is ON. ■ At the Information screen, check the 1200WR Receiver and the 1200W Acquisition module serial number.

Note

You can send a screen shot to GE Healthcare.

- Using the ***Print*** key on the keyboard, copy the screen to the Clipboard.
- Open *Word Pad* by selecting *Start -> Programs -> Accessories*.
- Insert the screen from the Clipboard with *Edit -> Paste*.
- Select the page orientation, using *File -> Print setup -> Landscape*.
- Print the page and fax it to GE Healthcare or save the page as a *Word Pad* document and send it via e-mail.

Data Backup

We recommend making one backup of the operating system, and daily backups of the CardioSoft software and of the patient data.

Virus Protection

To protect the CardioSoft system from viruses, the appropriate anti-virus software should be installed. Keep the virus definitions current to avoid virus infections.

CAUTION

PROGRAM DISTURBANCE—Be sure to disable (turn off) the anti-virus software auto-protect option during use of the CardioSoft software. This will prevent the virus protection program from interfering with the CardioSoft application while a patient test is running.

Note

It is advised that you initiate a manual virus scan weekly—at a time when a patient test is NOT running.

Direct Fax Transmission of Printer Documents

Instead of sending documents to the printer, they can be directly routed to another PC or to a fax machine. A modem with a serial port is required for this purpose. The modems recommended by GE Healthcare include the FAX software.

When installing the fax software from the original media, you can configure the fax port as the standard printer. With this setting, every print command is sent to the fax program. Enter frequently used fax numbers in the *Telephone Directory*. Select the *high* printer resolution and the landscape format. If the same image is transferred more than twice between two PCs, you must select the portrait orientation after the second transfer.

Sending a Fax

1. Display the screen to print.
2. Select the fax as the printer (for example, fax printer CAPTURE FAX BVZP).

The program converts the ECG to an image file. Depending on computer power, this may take a few minutes. The status indicator shows the page being converted. The fax software is activated automatically after the conversion.

3. Select the addressee (from the telephone directory).
4. Select *Send*. The status window and the audible signal from the modem indicate the transfer.

Note

All modems connected to the system must meet the requirements of IEC 60950. Furthermore, the regulations valid in the respective countries must be observed. The modem must be set up within the medical location, but not in the patient vicinity.

Warning

PATIENT HAZARD — Disconnect the patient from the system when the modem is connected.

Related Physician's Guides

For detailed information on specific topics, we recommend that you refer to these physician's guides:

- Physician's Guide to GE Stress Systems, Part No. 2051167-002
- TWA Physician's Guide, Part No. 2020044-067
- Physician's Guide to Audio ECG Assessment of Stress Tests, Part No. 2062179-002
- 12 SL Physician's Guide, Part No. 2056246-002

C Order Information

For your notes

Order Information

Subject to change. Always refer to latest list of accessories.

2062898-001	CardioSoft ECG analysis system incl. system cart, standard software, optionally with KISS suction pump
2062899-001	CardioSoft Upgrade to add hardware/software options

Optional Software Programs

45502401	Resting ECG Interpretation (RESI), requires RESM
45502901	Remote View (ERGM)
45502701	Storage of the Full Disclosure ECG (EGMO)
45503001	Data Storage on Network Server, < 3000 tests (NETS)
2014659-001	Data Storage on Network Server, < 15000 tests (NET2), requires NETS
2014659-002	Data Storage on Network Server, unlimited number of tests (NET3), requires NET2 and NETS
2014659-014	Arrhythmia Detection/Documentation (ARRY)
2014659-003	2D Waterfall Display (2DWF), requires ERG2
2014659-004	MUSE Browser (BRWS)
2014659-006	Data Export (EXPD)
2014659-007	Report Export as PDF File (EPDF)
2014659-008	Report Export as Word File (EWRD)
2014659-009	Display Configuration (DSPC)
2014659-010	In-Test Tabular Summary (ITBL)
2014659-011	In-Test Trend (ITRD)
2014659-012	Previous Test Retrieval (PRVT)
2014659-013	T-Wave Alternans (TWAA), requires EGMO

2014659-005	Risk Factors (RISK)
2014659-015	Data Export to External Archive (CDRW)
45503201	Exercise Test Expert Mode (ERG3), requires ERG2
45504001	ECG History (ECGH)
2014659-020	EMR Interface (XEMR)
2014659-026	DICOM Interface (DICM)
2014659-028	ST/HR Hysteresis (STHY), requires ERG2
2014659-029	Exercise Test Interpretation (EXTI), requires ERG2 and STHY

D Technical Description

Technical Specifications – CardioSoft System

Table 1. Performance Specifications – Signal Processing	
Item	**Description**
ST measurements - Resting	ST amplitudes, slope
ST measurements - Stress	ST amplitudes, slope, integral, index, ST/HR slope, ST/HR loops, ST/HR
E, J, and post-J point	Manual or computer selected
Signal processing technique	Incremental median updating
Baseline correction	ADS
Artifact/Baseline correction	ADS or Finite Residual Filter (FRF) algorithm
QRS detection and analysis	Based on automatic or manual lead selection
QRS trigger	TTL synchronization output
Arrhythmia detection	Automatic arrhythmia detection, documentation, and annotation
Full disclosure ECG	Up to 60 minutes of Full disclosure with event review both during and post acquisition
Reanalysis - Resting	Reanalyze after manual correction of median beats and measurements
Reanalysis - Stress	Post-test medians remeasurement from E, J, post-J point selections
ECG Analysis	Marquette 12SL ECG Analysis Program for Adult and Pediatric (optional)
Computerized Measurements	15-lead analysis includes measurements of user-selectable additional 3 leads
Additional ECG function	Vectorcardiography
Heart rate meter	30 to 300 BPM ± 10% or 5 BPM, whichever is greater. Heart rates outside this range will not be displayed.
Pre-Acquisition	Provides 10 seconds of instantaneous ECG acquisition

Table 2. Performance Specifications- Communication/Storage	
Item	**Description**
ECG Data Formats	GE Hi-Fidelity ECG, XML
Muse	MUSE Cardiology Information System Compatible (v7 or later) with bi-directional orders and ADT support
Muse web compatible for retrieval view and printing of Muse system data	Compatible for retrieval view and printing of Muse system data

Table 2. Performance Specifications- Communication/Storage	
Item	**Description**
CardioSoft Web	Compatible for report viewing
Data export	PDF export of final reports (auto export and custom file name) PDF export of Full Disclosure data Microsoft® Word export of configured reports XML or Microsoft Excel® export of specified data
EMR connectivity	Integrated with Centricity Practice Solution (CPS) EMR Other EMRs through MUSE Cardiology Information System (v8 or later) or GDT/BDT Interface
DICOM	Bidirectional, DICOM modality worklist/orders

Table 3. Display Type	
Item	**Description**
Monitored leads	▪ 12, 15 - Resting ▪ 3, 6, 12, 15 - Stress
Displayed leads	Number on screen 3, 6, 12 or 15
Display format	4 x 2.5, 4 x 2.5 + 1 rhythm, 2 x 6, 6 rhythm, 3 rhythm - Resting 4 x 2.5 + 1 rhythm, 2 x 6, 6 rhythm, 3 rhythm, 3 rhythm + medians, 3 rhythm + trend - Stress
Display speeds	25, 50 mm/s
Display sensitivity/gain	2.5, 5, 10, 20, 40 mm/mV - Resting 2.5, 5, 10, 20 mm/mV - Stress

Table 4. Safety	
Item	**Description**
Certification	▪ cTUVus Certification ▪ CE marking for Council Directive 93/42/EEC concerning Medical Devices ▪ Meets applicable IEC 60601-2-25 & IEC 60601-2-51 requirements for ECG safety & performance ▪ Meets IEC 60601-1-2 requirements for Electromagnetic Compatibility ▪ IEC 60601-1
Type of protection against electrical shock	Class II
Degree of protection against ingress of liquids	Ordinary
Handling of disposable supplies and other consumables	▪ Use only parts and accessories manufactured or recommended by GE Healthcare. ▪ Follow manufacturer's instructions for use for disposable/consumable product. ▪ Follow local environmental guidelines concerning the disposal of hazardous materials.

Table 4. Safety (Continued)	
Item	**Description**
Patient mode of operation	Continuous
Patient leakage current	<10 µA
Degree of protection against electrical shock	Type CF defibrillation protection for the patient cable (acquisition module)
Defibrillator recovery time	The recovery time from defibrillator discharge is less than 5 seconds.
Maintenance frequency	▪ Recommended user daily visual inspection and cleaning. ▪ Recommended six-month routine maintenance checks and test procedures performed by qualified technical personnel.

Table 5. Recommended Computer Specifications	
Item	**Description**
Microprocessor	Minimum Pentium® 4 class processor with 2 GHz
RAM	Minimum 2 GB
Hard drive	Minimum 80 GB and 4 GB of free space if used as a standalone system
SW installation	DVD-ROM drive or USB
Pointer	Mouse
Display resolution	Minimum: 1280 x 768 Maximum: 3840 x 2160
Interfaces	Minimum: 2 USB ports (1.1, 2.0, or 3.0) for each device using this type of interface, CD-RW, SD card, network interface card (recommended), Serial RS232 for each device using this interface type
Operating system	Windows 7 Professional (32 bit) with SP1 Window 8.1 Pro (64 bit) Windows 8.1 Enterprise (64 bit) Windows 10 Professional (64 bit) Windows 10 Enterprise (64 bit)
Printer	Equivalent to HP® P3015 dn (Customer Supplied)
Networking LAN	Wired and Wireless: 802.11 G (optional) TCP/IP interface
Additional software for export functionality	Microsoft Word and Excel (optional, Customer Supplied)
Citrix	Citrix Xen Desktop/Xen App 7.13 (Desktop Virtualization and/or Application Virtualization) without data acquisition (dedicated network bandwidth required) on Windows 7 Professional (64 Bit), Windows 8.1 Pro (64-bit), Windows 8.1 Enterprise (64 Bit), Windows 10 Pro (64-bit), Windows 10 Enterprise (64 Bit)

Table 6. CardioSoft Server Specifications	
Item	**Description**
Microprocessor	Minimum Pentium 4 class processor with 2 GHz
RAM	Minimum 2 GB
Hard drive	Minimum 80 GB and 10GB of free space
SW installation	DVD-ROM drive
Operating system	Windows Server 2008 R2 (64 bit) with SP1 Windows Server 2012 (64 bit) Windows Server 2012 R2 (64 bit) Windows Server 2016 (64 bit)
Web	Internet Information Server (IIS)
Additional software for export functionality	Microsoft Word and Excel (optional)
Networking LAN	Ethernet or Fast Ethernet Network Interface Controller

Table 7. Performance Specification - Data Acquisition CAM CONNECT 14	
Item	**Description**
Technology	Type CF, Defibrillation-Proof Defibrillation protection: Per IEC 60601-2-25
Dynamic Range	AC Differential ± 5mV, DC offset ±300 mV
Technology	Type CF, De-fibrillation-Proof De-fibrillation protection: Per IEC 60601-2-25
Dynamic Range	AC Differential ± 5 mV, DC offset ± 300 mV
Common Mode Rejection	>130 dB (>100 dB with AC filter disabled)
Input Impedance	>10MΩ @ 10 Hz, defibrillator protected
Patient Leakage	<10 µA
Analog to Digital Conversion	Bandwidth: DC to 500 Hz; Sample rate: 2 ksps; Resolution: 0.1192 µV
Down Sampled ECG waveform	Bandwidth: 0.04 to 150 Hz; Sample rate: 2 ksps; Resolution: 1.22 µV
Input to ECG Analysis	Bandwidth: 0.04, 0.56 ZPD to 150 Hz; Sample rate: 500 sps; Resolution: 5 µV/LSB
Pacemaker waveform	Bandwidth: 23.5 Hz to 10.5 kHz; Sample rate: 75 ksps; Resolution: 11.8 µV

Table 7. Performance Specification - Data Acquisition CAM CONNECT 14	
Pace Detection	Duration: 0.2 ms to 2.2 ms Amplitude: 2 mV to 700 mV Separation: 1 ms or greater
Quality Indicators	Real-time Hookup Advisor with LED lead quality indicators
Remote control	ECG acquisition button
Ingress Protection Level	IPx4
Noise	< 15 µV (-3 dB) bandwidth
High pass filter	0.04
Additional report filters	20, 40, 100, 150 Hz (selectable)
Line filter	50.0 or 60.0 Hz notch filter (selectable)
Operating Voltage	5.0 V DC
Operating Current	1 A
Type of protection against Electric Shock	Class II

Table 8. Technical Specification - CAM-USB, CAM-USB A/T, CAM-USB A/T KISS, KISS Multilead, CAM CONNECT 14	
Item	**Description**
Operating conditions	
Temperature	+10 to +40 °C (+50 to 104 °F)
Humidity	25 to 95 % RH non-condensing
Pressure	700 to 1060 hPa
Storage/Transport conditions	
Temperature	-30 to +70 °C (-22 to 158 °F)*
Humidity	10 to 95 % RH non-condensing
Pressure	500 to 1060 hPa

Spirometry Technical Specification

For information on Spirometry Technical Specification see Spiro-SP True Flow™ Sensor Instructions for Use.

Ambulatory Blood Pressure (ABP) - TONOPORT Technical Specifications

For information on TONOPORT V and TONOPORT VI Technical Specification see TONOPORT V - Ambulatory Blood Pressure System Service Manual and TONOPORT VI - Ambulatory Blood Pressure System Service Manual respectively.

Wireless GEH-ECG 1200

For information on Wireless GEH-ECG 1200 see Wireless GEH-ECG 1200 User Guide.

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